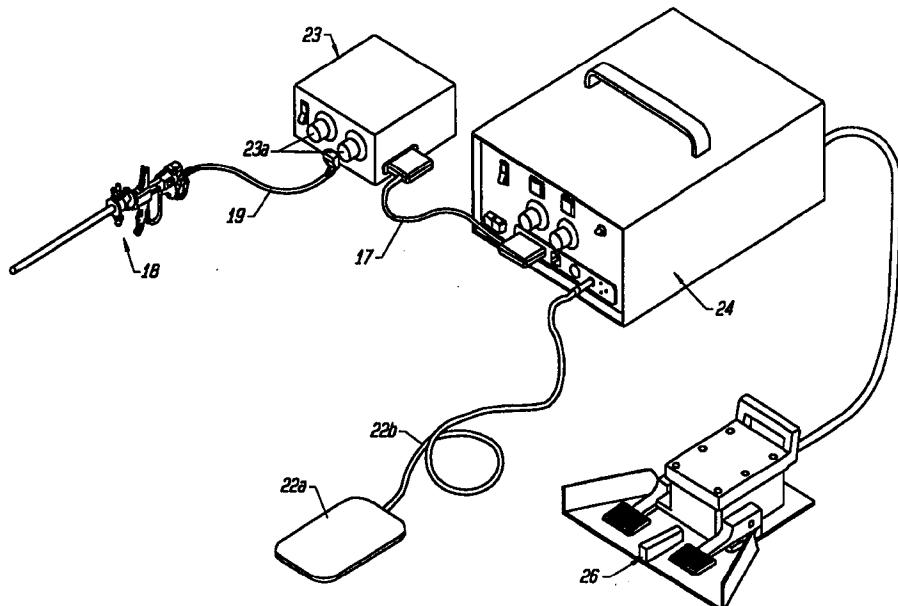


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/32		A1	(11) International Publication Number: WO 98/38932 (43) International Publication Date: 11 September 1998 (11.09.98)
(21) International Application Number: PCT/US98/04495			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 6 March 1998 (06.03.98)			
(30) Priority Data: 08/813,601 7 March 1997 (07.03.97) US			
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 08/813,601 (CIP) Filed on 7 March 1997 (07.03.97)			
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(54) Title: RESECTOSCOPE ELECTRODE ASSEMBLY WITH SIMULTANEOUS CUTTING AND COAGULATION



(57) Abstract

An electrode assembly for a resectoscope has a cutting electrode with a distal portion and a coagulation electrode with a distal portion. A support frame is connected to the cutting and coagulation electrodes. The cutting and coagulation electrodes are configured to be coupled to a splitter box. The splitter box receives an input from a single energy source. The cutting and coagulation electrodes simultaneously receive sufficient energy from the single energy source to the cutting electrode to cut tissue and to the coagulation electrode to coagulate tissue.

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RESECTOSCOPE ELECTRODE ASSEMBLY WITH SIMULTANEOUS CUTTING AND COAGULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application is a continuation-in-part of Serial No. 08/577,598 filed December 2, 1995, which is a continuation-in-part of Serial No. 08/445,597, filed April 22, 1995.

BACKGROUND OF THE INVENTION

Field of the Invention

10 This invention relates generally to resectoscope electrodes, and more particularly, to a resectoscope electrode assembly that simultaneously cuts and coagulates and uses only one power source.

Description of Related Art

15 BPH is a benign overgrowth of the prostate gland that is situated at the bladder outlet. BPH is one of the most common conditions affecting men over the age of 50. The incidence increases with age and reaches 80 to 90% at 80 years. In the majority of patients, the BPH causes no symptoms. However, in a certain percentage of patients, the BPH will slowly and progressively obstruct the urinary outflow causing voiding symptoms of bladder obstruction and irritation. Furthermore and yet in a smaller percentage, these symptoms progress to cause complete urinary retention, urinary infections, bladder stones, and kidney damage. The decision to treat or not to treat patients is governed by the presence and absence of symptoms and their severity. Therefore, in the far majority of BPH patients (approximately 70%) who remain asymptomatic, no treatment is needed. In the symptomatic BPH patients, a wide variety of treatment strategies are available.

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25 There are two groups of surgical therapies for BPH based according to the anesthesia requirement. The first group requires general or spinal anesthesia and

includes open prostatectomy, transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), transurethral vaporization of the prostate (TVP), visual laser assisted prostatectomy (V-LAP), contact laser prostatectomy, prostate balloon dilation, and intra-prostatic stents. TURP is the "gold standard" treatment. It has been the most efficacious and durable of all the surgical treatments, with a success rate of 80 - 90%.

5 The prostate is a highly vascular organ which bleeds during resection (TURP). Bleeding causes a decrease in visual clarity which in turn leads to a variety of 10 intraoperative difficulties with undesirable consequences. The bleeding is the main offending factor responsible for the majority of the problems: Figure 1 is a flow chart 15 listing the complications of the standard TURP.

A typical resectoscope for transurethral resection consists of four main 20 elements. The first element is a rigid telescope for observing the interior of the urinary tract where the surgical procedure is performed. The telescope comprises an 25 objective lens and a series of relay lenses housed within an endoscope barrel or stem, the stem being connected to an eyepiece housing containing suitable lenses for proper magnification. The second element takes the form of a handle assembly commonly referred to as a working element. The working element can serve as the means for connecting electrosurgical current from an electrosurgical generator to the third element, an electrode assembly. The working element is also capable of sliding the electrode assembly along the longitudinal axis of the resectoscope. The combination of the telescope, working element, and electrode assembly is locked into a fourth element, a resectoscope sheath. The sheath consists of a tube and a union body and lock assembly. In the operative procedure the entire resectoscope is placed into the 30 urethra.

The usual resectoscope electrode assembly is in the form of a U-shaped tungsten wire loop, the ends go to one or more wires that fit in a socket in a working element of the resectoscope for current conduction. The wire arms usually merge at their proximal ends and are jointed to an electrode lead extending back to the working element of the instrument. To brace the cutting loop so that it remains uniformly

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spaced from the telescope stem, a metal spacing sleeve is commonly provided between the telescope stem and either parallel electrode arms or the distal portion of the electrode lead immediately adjacent to those arms. The metal spacing sleeve is slidable along the telescope stem as the electrode assembly is advanced and retracted and, because of the direct contact between the spacing sleeve and the telescope stem, it has been necessary in the past to insure adequate insulation between the electrode and the sleeve.

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To date, all new and alternative surgical therapies have generally failed to exhibit similar efficacy and durability, however, they have shown certain advantages in minimizing morbidity, the amount of blood loss that is experienced and are easier to perform. There is a need for a safer and less morbid approach than TURP that exhibits similar durable efficacy.

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The second group of surgical therapies require local anesthesia without the need for general or spinal anesthesia. These treatments utilize different energies to deliver thermal therapy to the prostate. They include transurethral microwave thermotherapy (TUMT), transurethral thermal-ablation therapy (T3), high intensity focus ultrasound (HIFU), laser delivered interstitial thermal therapy (LDIT), and transurethral needle ablation of the prostate (TUNA). These treatments are less morbid than conventional TURP. Such thermal therapies are currently under investigation and will require completion of phase three trials and FDA approval before they make their debut into the market.

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There is a need for a bloodless TURP apparatus, as shown in Figure 1, thus alleviating virtually all of the problems of the standard TURP devices. This can be achieved in a TURP apparatus which provides simultaneous cutting and coagulation. There is a further need for an assembly suitable for use with a resectoscope which provides simultaneous cutting and coagulation with the cutting and coagulation electrodes configured to be coupled to a single energy source. There is still a further need for an resectoscope assembly that provides simultaneous cutting and coagulation while minimizing the creation of a bipolar current between the cutting and the coagulation electrodes.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the invention to provide an electrode assembly for a resectoscope that includes a coagulation electrode distal portion that operates simultaneously with a cutting electrode distal portion.

5 Another object of the invention is to provide an electrode assembly for a resectoscope that includes a coagulation electrode, a cutting electrode, and a single power source that supplies power to both electrodes.

10 Still another object of the invention is to provide an electrode assembly for a resectoscope that includes a coagulation and cutting electrode with a single distal portion with different current densities that simultaneously cuts and coagulates and includes a single power source.

15 Another object of the invention is to provide an electrode assembly for a resectoscope that includes a coagulation electrode and a cutting electrode, each with a distal end distal portion configuration, and each with different current densities.

20 Yet another object of the invention is to provide an electrode assembly for a resectoscope which includes cutting and coagulation electrodes while minimizing the creation of a bipolar current between the two electrodes.

25 Still another object of the invention is to provide an electrode assembly for a resectoscope which includes cutting and coagulation electrodes that are configured to be coupled to a splitter box that provide simultaneous cutting and coagulation while minimizing the creation of a bipolar current between the two electrodes.

These and other objects of the invention are achieved in an electrode assembly for a resectoscope that has a cutting electrode with a distal portion and a coagulation electrode with a distal portion. A support frame is connected to the cutting and coagulation electrodes. The cutting and coagulation electrodes are configured to be coupled to a splitter box. The splitter box receives an input from a single energy source. The cutting and coagulation electrodes simultaneously receive sufficient energy from the single energy source to the cutting electrode to cut tissue and to the coagulation electrode to coagulate tissue.

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In one embodiment of the invention, the splitter box includes a first coil and a second coil. The first coil is configured to receive the input from the single power source and the cutting electrode is coupled in parallel with the first coil. The second coil is configured to provide current to the coagulation electrode. The first and second coils may be inductively coupled to each other to minimize creation of a bipolar current between the cutting and coagulation electrodes.

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In another embodiment, the splitter box includes a first coil and a second coil inductively coupled to each other in order to minimize a creation of a bipolar current between the cutting and coagulation electrodes. The first coil receives the input signal from the single power source and the coagulation electrode is coupled in parallel with the first coil. The second coil provides current to the cutting electrode.

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In a further embodiment, the splitter box includes a first coil, a second coil and a third coil inductively coupled to each other to minimize a creation of a bipolar current between the cutting and coagulation electrodes. The first coil receives the input from the single power source and the second coil provides current to the cutting electrode. The third coil provides current to the coagulation electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a flow diagram illustrating the complications of the standard TURP procedure.

Figure 2(a) is a perspective view of one embodiment of the electrode assembly of the present invention.

Figure 2(b) is an end-view of the electrode assembly 2(a) along lines 2(b) - 2(b).

Figure 2(c) is a cross-sectional view of the electrode assembly 2(a) taken along the lines 2(c) - 2(c).

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Figure 2(d) is a cross-sectional view of one embodiment of the electrode assembly 2(a) taken along view lines 2 - 2 , with the cutting and coagulation electrode distal portions having different current densities by reducing the contact surface between the electrode and tissue at a given power level.

Figure 2(e) is a cross-sectional view of one embodiment of the electrode assembly 2(a) taken along view lines 2 - 2, with the cutting and coagulation electrode distal portions having different current densities by reducing the contact surface between the electrode and tissue at a given power level.

5 Figure 2(f) is a cross-sectional view of one embodiment of the electrode assembly 2(a) taken along view lines 2 - 2, with the cutting and coagulation electrode distal portions having different current densities by reducing the contact surface between the electrode and tissue at a given power level.

10 Figure 2(g) is a cross-sectional view of one embodiment of the electrode assembly 2(a) taken along view lines 2 - 2, with the cutting and coagulation electrode distal portions having different current densities, by changing the material of the electrode to limit the current flow through the electrode.

15 Figure 2(h) is a cross-sectional view of a single cutting and coagulation distal portion that cuts and coagulates simultaneously, and has different current densities for the cutting and coagulation sections of the single distal portion by having a segmented electrode composed of multiple layers of alternating metal and insulation.

Figure 3(a) is a perspective view of a second embodiment of electrode assembly of the present invention.

20 Figure 3(b) is an end-view of the electrode assembly 3(a) along lines 3(b) - 3(b).

Figure 3(c) is a cross-sectional view of the electrode assembly 3(a) taken along the lines 3(c) - 3(c). Figure 3(d) is a cross-sectional view of the electrode assembly 3(a) taken along the lines 3(d) - 3(d).

25 Figure 3(e) is a cross-sectional view of the electrode assembly 3(a) taken along the lines 3(e) - 3(e).

Figure 4(a) is a perspective view of the resectoscope

Figure 4(b) is an end-view of the resectoscope 4(a) along lines 4(b) - 4(b).

Figure 5(a) is a diagram of the resectoscope, power supply, and the converter of the present invention.

Figure 5(b) is a diagram of the resectoscope, power supply, and the present invention of transformer conduit unit (without the converter).

Figure 6 is a schematic diagram of the electronics for a converter (106) of the present invention of Figure 5(a).

5 Figure 7 is a schematic diagram of electronics of one embodiment of the transformer (90) of Figure 5(a) being a monopolar device coupled to a bipolar outlet of an RF power source.

10 Figure 8 is a schematic diagram of electronics of a second embodiment of the transformer (90) of Figure 5(a) being a mono-polar device coupled to a bipolar outlet of an RF power source.

Figure 9(a), 9(b), 9(c), and 9(d) are schematic diagrams of electronics of third, forth, fifth, and sixth embodiments of the transformer (90) of Figure 5(a) being a bipolar device coupled to a bipolar outlet of an RF power source.

Figure 10 is a schematic diagram illustrating the inclusion of a splitter box.

15 Figure 11 is a schematic diagram illustrating the inclusion of a splitter box, a cutting electrode ground pad and a coagulation electrode ground pad.

Figure 12 is a schematic diagram that includes a splitter box, a cutting electrode loop and a coagulation electrode loop.

Figure 13(a) is a graph illustrating a voltage applied to the cutting electrode.

20 Figure 13(b) is a graph illustrating a voltage applied to the coagulation electrode.

Figure 14 is a graph illustrating that the cutting and coagulations are in phase.

Figure 15 is a partial circuit diagram of an RF power source used when the cutting and coagulation electrodes are in phase.

25 Figure 16 is a schematic diagram of a monitoring circuit that monitors voltage and impedance of the cutting and coagulation device of Figure 2(a).

Figure 17 is a graphical illustration of a coagulation waveshape of an isolator transformer of Figure 16.

30 Figure 18 is a graphical illustration of a cut waveshape of an isolator transformer of Figure 16.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention is an electrode assembly for a resectoscope and includes, a cutting electrode and a coagulation electrode, both with distal portions that can have a variety of different geometries including but not limited to loops and roller balls.

5 The functional aim of the electrode assembly is to achieve simultaneous tissue cutting and coagulation during surgery while minimizing the creation of a bipolar current between the two electrodes. The electrode assembly receives its energy from a single power supply source energy that may be coupled to a splitter box. The conventional primary energy generated by the power supply source is converted and split into two 10 separate energies, one for each of the distal loops of the electrode assembly. A purposely designed energy converter or transformer conduit unit is responsible for this. This permits the use of a single energy source to supply two given energy powers to the two electrode assembly loops to allow them to have different functional properties operating simultaneously, one for tissue cutting and another for tissue 15 coagulation. Furthermore, a variety of electrode assembly distal portion designs are presented which are based on but not limited to (i) materials, (ii) geometries, (iii) dimensions, or (iv) insulations to allow additionally functional adjustments and alterations. A variety of energy sources can be utilized including but not limited to RF, microwave, thermal, and the like.

20 In another embodiment of the invention, the electrode assembly has only one loop, which simultaneously cuts and coagulates. The loop has a coagulation portion with a lower power density than a cutting portion. This is achieved by a variety of methods, including but not limited to using different (i) materials, (ii) geometries, (iii) dimensions, or (iv) insulation.

25 In yet another embodiment of the invention, a resectoscope is disclosed which includes the electrode assembly, a resectoscope sheath, a working element, and a visualization apparatus.

30 Further, as compared to devices currently used for standard TURP's, the present invention has: increased visual clarity; a performance that is easier for the urologist; a lower risk of entering venous sinus; a lower risk of further bleeding;

decreased potential for blood transfusions; less fluid irrigation and bladder distention; less risk of TURP syndrome; lower risk of capsular penetration and subsequently less risk of fluid extravasation into the abdomen; lower risk of urinary sphincter injury and subsequently less risk of urinary incontinence; lower risk of ureteral orifice injury and subsequently less risk of ureteral obstruction and vesicoureteral reflux; shorter 5 operative time; less need for bladder catheterization and Foley traction postoperatively; lower risk of postoperative scarring and bladder neck contracture; less need for postoperative bladder irrigation; a shorter duration for postoperative Foley catheterization; a shorter hospital stay; and an associated cost less than the 10 standard TURP.

For purposes of this disclosure, the word "simultaneous" means, (i) RF-energy is supplied at the same time to the cutting and coagulation electrode distal portions, (ii) RF energy is supplied to both distal portions in less than 1 second, (iii) within the same hand action, e.g., on a forward stroke or on a back stroke, energy is only supplied in the cutting mode, and on the other stroke it is only supplied in the coagulation mode, (iv) when energy is delivered to the distal portions the coagulation distal portion has a thermal or RF spread of energy that reaches the cutting distal portion when it is cutting, (v) two currents go out to both distal portions at the same time and (vi) the transfer of thermal energy from the coagulation electrode to the site 15 of the cutting electrode occurs in less than one (1) millisecond. It will be appreciated that thermal spread from the coagulation distal portion is controllable. The higher the energy, the greater the spread. The lower the energy, the lower the spread. It is possible to have the RF energy spread extend beyond the cutting electrode's physical 20 location.

25 The electrode system and resectoscope of the present invention can be operated in bipolar or monopolar modes. Bipolar is particularly suitable when the two electrodes are closer together, and in those instances when RF energy spread between the two electrodes is desired to be limited or controlled. The shorter the distance between the two electrodes, then RF energy spread does not appreciably extend 30 beyond the electrodes. This is particularly useful in those instances where that RF

energy spread to surrounding or adjacent tissues or structures this can lead to an undesirable result.

Further, the present invention can be employed in gastrointestinal endoscopic surgery, general laparoscopic surgery, thoracoscopy, head and neck surgery, orthopedics, gynecology and the like. A gastrointestinal resectoscope can be used to resect intestinal tumors and other lesions endoscopically. The electrode system and resectoscope of the present invention provides safer resection of these tumors and lesions with improved visualization and reduced morbidity and mortality.

Laparoscopic excisional biopsies, resection, dissection of lesions and surgical planes involving internal organs, such as the liver the like, can be achieved more readily with fewer complications. Head and neck applications include but are not limited to the oral cavity, throat, larynx, pharynx, sinuses, ears and pulmonary system. Biopsies and excisions of lesions with bleeding potentials including but not limited to hemangiomas, nasal polyps, cancers and the like, can be performed using the present invention. Endoscopic orthopedic surgery applications include but are not limited to resections of prolapsed and ruptured vertebral discs, torn joint cartilage, scars, spurs and the like. Gynecological surgery includes excision for endometriosis lesions, tumors, lymph nodes, and the like.

Referring now to Figures 2(a), 2(b), and 2(c) which illustrate the electrode assembly, the electrode assembly in its distal portion comprises two electrode loops, a cutting loop 10 and a coagulation loop 12. Suitable electrode loop geometry include but not limited to, radial, circular, elliptical, curved, rounded, bowed, arc, arch, crescent, semicircular, malleable and roller (whirler, revolver, rotary) cylinder, and can also include a roller ball. A microporous membrane, coupled to an infusion source such as an electrolytic solution (saline), can be positioned between cutting loop 10 and coagulation loop 12. In one embodiment, a plurality of roller balls are included to form a loop with any of the previously mentioned geometries. The loop size diameter can be 3 mm (9 French gauge) to 10 mm (30 French gauge), or any size that will fit in a commercially available resectoscope (8-28 French gauge). Cross-section shapes of the wires include, circular, hemicircular, any portion of a circle,

square, triangular, shapes such as hexagon, octagon, etc. flat plate, and combination of the above. The wire can include horizontal or longitudinal grooves. The cross-sectional diameter of the wire can be from about 0.25 to 4 mm. The size of the roller can be 0.25 to 4 mm. The cutting loop 10 and the coagulation loop 12 can be in a fixed distance relationship to each other. The distance between the two loops can range between 1 to 6 mm. This permits sufficient time for the cutting loop 10 to cut tissue, while simultaneously coagulation loop 12 is coagulating tissue at a slight distance away. The proper separation distance permits the two loops from effectively cutting and coagulating simultaneously without interfering with each other.

Cutting loop 10 is continuous with wire limbs 14 & 16. Coagulation loop 12 is continuous with wire limbs 20 & 22. Wires 14 and 20 terminate in end caps 34 and 36 respectively which serve in connecting them to the energy supply source. Wires 16 and 22 terminate blindly along the electrode assembly body where they are individually insulated from the rest of the electrode assembly components. Through end cap 34, the energy is transmitted to wire 14 to reach cutting loop 10. Through end cap 36, the energy is transmitted to wire 20 to reach coagulation loop 12. Electrode wires 16 and 20 are individually packaged inside steel tubing 26 and outside insulation sleeve 28, all of which are encased within housing sleeve 30. Electrode wires 14 and 22 are similarly packaged inside steel tubing 26 and outside insulation 28 and encased within housing sleeve 30. The thickness of the insulation sleeve is in the range of 0.001 to 0.100 inches. The housing sleeves 30 extend along the electrode assembly to variable distances to permit sufficient support and rigidity to its inside contents.

Optical guide sleeve(s) 32 is part of the electrode assembly that is a guide tube for optics, including but not limited to relay lenses and the like, and provides a supporting frame for electrode loops 10 and 12, electrode wires 14, 20, 16, 22, steel tubing 26, and housing sleeves 30. Optical guide sleeve 32 can be cylindrical, tubular, or a portion of a cylinder or tube. Further, optical guide sleeve 32 can be singular or multiple in number. It can range from 0.1 mm to 30 cm, i.e., it can extend from the proximal to the distal ends of electrode assembly. Optical guide sleeves 32 are

mounted to housing sleeves 30 anywhere along the length of the electrode assembly depending on the design of the resectoscope.

Cutting loop 10 and coagulation loop 12 can be made of a variety of electrical conductive materials including but not limited to tungsten, its alloys, stainless steel and the like. A preferred material is a tungsten wire. Their corresponding electrode wires 14, 20, 16, 22 can be similarly made of variety of electrical conductive materials. Insulating sleeves 28 can be made of a dielectric material including but not limited to, (i) fluopolymers, (ii) polyimide, (iii) polyamide, (iv) polyaryl sulfone and (v) silicone plastic. Steel tubing 26, housing sleeve 30 and optic guide sleeve 32 can be made of stainless or corrosion resistant material such as stainless steel, and the like.

Referring now to Figures 2(d) through 2(g) the cross sections of cutting loop 10 and coagulation loop 12 are illustrated in a variety of embodiments. In Figures 2(d) through 2(g) two loops of different power levels are created by applying insulation (e.g. Teflon, oxides, paint) selectively. In each embodiment, the current density for coagulation loop 12 is lower than the current density of cutting loop 10. In Figure 2(d) insulation is applied to a contact surface of coagulation loop 12. The electrodes are the same size in Figure 2(d), while the electrodes in Figure 2(e) have different sizes. In Figure 2(e) coagulation loop 12 has an increased surface area. In Figure 2(f) coagulation loop 12 has insulation applied substantially around it. In Figure 2(f) there is increased size and increased path. Referring now to Figure 2(g), area is increased by providing coils.

Referring now to Figure 2(h) cutting and coagulation functions are combined into a single distal loop with a sharp cutting edge that is a hotter point and a larger coagulation surface at the other side.

Refer now to Figures 3(a), 3(b), 3(c), 3(d), and 3(e) which illustrate an alternative electrode assembly. In this embodiment, a single arm conductor rod transfers and transmits two electrical currents through rods 18 & 24 to the body via cutting electrode 10 and coagulation electrode 12. Within crimp 38 inside housing 40, rod 18 connects to electrode wire 14 which extends distally to form cutting loop 10 and returns back as electrode wire 16. In a similar fashion within crimp 38 inside

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housing 40, rod 24 connects to electrode wire 20 which extends distally to form coagulation loop 12 and returns back as electrode wire 22. Both electrode wires 16 & 22 return back into crimp 38 where they end blindly inside and get insulated from the rest of the electrode assembly components. On their way distally to form the cutting loop 10 and the coagulation loop 12, each electrode wire lies inside individual steel tubing 26 and insulation 28.

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Proximally, rod 18 resides within hollowed rod 24 with inner insulating sleeve 42 in between. Outer insulation sleeve 44 covers the outside of rod 24. Housing sleeve 46 surrounds segments of the outer insulation 44 to allow support and to add body stiffness to the electrode assembly. At the proximal end of the electrode assembly, rod 18 and 24 are exposed free of the insulation sleeves 42 & 44 to allow connection to the energy supply source. The purpose of the proximal single arm electrode assembly is to allow its use in a variety of commercially available resectoscopes. Insulating materials can be any of the commonly used plastics or other non-conducting materials accepted for medical devices. Further includes, a lock catch 48 and optic guide sleeve 32.

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Referring now to Figures 4(a) and 4(b) which illustrate the resectoscope. The resectoscope includes the following parts: a sheath 50, a working element 62, and a visualization apparatus 74. These parts together with the electrode assembly fits in with each other to form a functional resectoscope. When assembled, the cutting and coagulation loops 10 & 12 of the electrode assembly are positioned within the sheath lumen 54 at the distal end of the resectoscope sheath 52.

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The resectoscope sheath 50 has a sheath lumen 54 that extends substantially along the entire length of the sheath from its distal end 52 to its proximal end 60. Near its proximal end 60, lie an inflow socket 56 and an outflow socket 58 used to circulate fluid irrigation during surgery.

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The resectoscope working element 62 of the resectoscope include the following elements (i) a thumb grip handle 64, (ii) a finger grip handle 66, (iii) a spring mechanism 68 located between the two handles this serve in maintaining the handles apart, i.e., the electrode assembly distal portions inside the sheath; further

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spring mechanism 68 also serves to restore this position following manual deployment out of the electrode assembly distal loops, (iv) an internal socket 70 where the proximal end of the electrode assembly is plugged into and secured in for electric current connection and transmission, and (v) an external socket 72 for plugging in an external cable that transmits electric currents from the converter and energy supply source. All connections are insulated to prevent dissipation of the electric current. The electrode assembly fits into and through the working element 62.

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The resectoscope visualization apparatus 74 includes a proximal end 76 with an eye piece, a socket 78 for attachment of a light source cable, a rod lens 80 and a distal end 82. The rod lens 80 is the actual body of the visualization apparatus 74 and extends from the proximal end 76 to the distal end 82.

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The optical guide sleeve 32 of the electrode assembly, (i) guides the placement and attachment of the rod lens to the electrode assembly and stabilizes the two together, (ii) maintains and supports the correct and proper position of the electrode assembly through the sheath lumen 54 and (iii) allows the electrode assembly to longitudinally slide in and out parallel to the lens rod 80 during usage and maintains this positional relationship throughout the surgical procedure.

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Referring now to Figure 5(a), resectoscope 86 receives power from energy supply source 110. The energy supply source is activated by foot control 112. The energy generated from energy supply source 110 is transported through electric cable 84 to converter 106 where the energy is split into two given energy power levels. The ratio of energy split and the levels of energy power exiting converter 106 can be adjusted manually on its front panel 108 that allow simultaneous cutting and coagulation. The primary mode of current delivery is cut and coagulate but can also include other modes such as (i) cut and cut, (ii) coagulate and coagulate and other combinations as determined by the controls on front panel 108. Electric cable 88 transports the split energies into resectoscope 86 to supply two loops (loop 10 & 12) of its electrode assembly for simultaneous cutting and coagulation. By using two different current densities in loops 10 and 12 or in a single loop as in embodiment 2(h), only one energy supply source 110, is necessary. Converter 106 permits

substantially any commercially available energy supply sources to be utilized with the present invention. Suitable RF power supplies are commercially available from Valley Labs, Erbe, as well as from other commercial vendors. Other energy sources can also be used including but not limited to microwave, ultrasound, thermal and other electromagnetic sources.

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Referring now to Figure 5(b), resectoscope 86 receives power from energy supply source 110 through transformer/conduit unit 90. The energy supply source is activated by foot control 112. The transformer/conduit unit 90 consists of an electrical conduit (cable) 94 that plugs to the power supply source 110 through its proximal end adapter 96. The distal end of the electrical conduit plugs into resectoscope 86. Along the electrical conduit, and incorporated into it, lies transformer unit 92. In Figure 5(b), the transformer unit 92 is located towards the distal end of the transformer/conduit unit 20 but is not limited to this location. The transformer unit 92 can be located anywhere along the length of the transformer/conduit unit 90. A grounding pad 100 is placed on the patient's skin and attached to it is grounding cable 102. The grounding cable 102 has adapter 104 at its proximal end which connects to the energy supply source 110. Adapter 104 also connects to adaptor 96 of transformer/conduit unit 90 through connecting cable 98.

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As shown in Figure 6 bridge 114 rectifies the RF signal, which is then filtered by filter 116, and regulated by a regulator 118 which provides a supply voltage to the control electronics for two channels. The two control channels are identical. RF from an external generator is delivered symmetrically to first and second FET device pairs 120 and 122 which act as voltage controlled power resistors. A gate voltage is generated by sampling an output from current sensors 124 and 126, and bridge rectifiers 128 and 130, and comparing it to a preset level. The preset level is obtained through six position switches 132 and 134, and resistor networks 136 and 138 connected to Vcc power supply as a divider. Amplifiers 140 and 142 compare the two levels and the difference drives FET pair gates 120 and 122. Output RF to cutting loop distal portion 10 and coagulation loop 12 is provided through isolation

transformers 144 and 146 that also bias first and second FET pairs 120 and 122. Capacitors on the output provide DC blocking to further protect the patient.

Referring now to the cable schematics of Figure 7 only one power supply 110 is used without electronic control to maintain the power level. Cut or coagulation electrode has a variable center tap 152, permitting selectivity of splitting with a given amount of power from power supply 110. In Figure 8, the cable permits monopolar remote control. Included is a remote control switch 148. The position of switch 148 is transferred through conductors inside the cable to a relay driver 150 which switches center taps 152 to achieve a desired combination.

Figures 9(a), 9(b), 9(c), and 9(d) illustrate bipolar embodiments. The embodiment illustrated in Figure 9(a) and 9(d) is not pre-wired, while the cable in Figure 9(b) and 9(c) is pre-wired. Figures 9(a), 9(b), 9(c), and 9(d) illustrate that power is received by a bi-polar outlet even though it operates in a mono-polar mode with a groundpad.

The underlying principle on which the embodiment in Figures 7, 8, 9(a), 9(b), 9(c), and 9(d) are based, is the ability to split a given RF power level at a transformer primary into two or more secondary outputs according to the ratio of the individual secondary windings to the windings of the primary. Since the secondary windings deliver the RF power to monopolar electrodes in the resectoscope of this disclosure, a ground return must be provided when the bipolar output of an ESG is used by connecting a ground to the reference tap 98 in Figure 5(b).

In operation, power supply 110 is set to a power level greater than the maximum required level by at least 5 watts, in order to power the electronics. Individual power level for each channel is preset by control switches. When power supply 110 delivers power, each channel delivers an attenuated level of power according to the switch setting.

Referring now to Figure 10, cutting electrode 10 and coagulation electrode 12 are illustrated with first and second generator outputs 154 and 156 respectively. bipolar current 174 that are received by a splitter box 158 that is coupled to generator 160. A patient, generally denoted as 162, represents some level of impedance and a

ground or return electrode 164 is positioned on a skin surface. In one embodiment, return electrode 164 includes a cutting dispersion pad 166 and a coagulation dispersion pad 168.

Cutting current 170 is delivered from cutting electrode 10 to patient 162 while simultaneously coagulation current 172 is delivered from coagulation electrode 12 to patient 162. A bipolar current 174 is also flowing between cutting electrode 10 and coagulation electrode 12. To reduce, minimize and/or eliminate bipolar current 174 ground pad electrode 164 is coupled to splitter box 158.

As illustrated in Figures 11 and 12, an isolation transformer 176 is included in splitter box 158. Isolation transformer 176 isolates coagulation dispersion pad 168 and coagulation electrode 12 from cutting dispersion pad 166 and cutting electrode 10 creates an isolated circuit and eliminates bipolar current 174. Splitter box 158 takes a cutting signal 178 and places it across cutting electrode 10 and cutting dispersion pad 166 and is hardwired at 180. Splitter box 158 takes a coagulation signal 182 and places it across coagulation electrode 12 and coagulation dispersion pad 168 and is hardwired at 184. There is no direct connection between the between cutting electrode 10 and coagulation electrode 12 and two separate circuit loops 186 and 188 respectively are provided. When current is supplied simultaneously from power source 160 to cutting electrode 10 and coagulation electrode 12 isolation transformer 176 provides simultaneous electrical isolation. There is no interaction between cutting electrode 10 and coagulation electrode 12 which eliminates any bipolar interaction between the two.

Referring now to Figures 13(a) and 13(b), there are two types of wave forms in electrosurgery. A cutting waveform 190 is usually a continuous sine wave of a given frequency, including but not limited to 460 KHz which can be used for cutting a variety of different tissues. A coagulation waveform 192 is typically a discontinuous waveform with a fairly large voltage peak followed by a long off time and then another large voltage peak.

In one embodiment of the present invention, bipolar current 174 is reduced and in some cases eliminated when coagulation waveform 192 is in phase with cutting

waveform 190 during non-shut off times as illustrated in Figure 14. Initially coagulation waveform 192 is in phase with cutting waveform 190, then shuts off and when it comes back it coagulation waveform 192 is in phase with cutting waveform 190.

5 Referring now to Figure 15, cutting and coagulation waveforms 190 and 192 respectively are in phase and there is no bipolar current between the cutting and coagulation electrodes 10 and 12 respectively. Because there is no voltage potential between the cutting and coagulation electrodes 10 and 12 they are at the same potential.

10 Figure 16 illustrates a circuit 193 which monitors voltage and impedance of the dual loop system of cutting loop 10 and coagulation loop 12 shown in Figure 2(a). Circuit 193 provides a safety feature which permits the dual loop system at different tissue sites. At each site, there may be a different upper energy limit. Circuit 193 monitors voltage and impedance, and hence controls the amount of energy delivered, 15 at these different sites so that there is no damage done at the selected site. Circuit 193 reduces leakage current, measures impedance at cutting loop 10, voltage at coagulation loop 12, can cut off power delivery to cutting loop 10 while maintaining power delivery to coagulation loop 12 and may also cut off power delivery to cutting loop 10 when cutting loop 10 is not in contact with tissue. Cutting loop 193 includes 20 a bridge rectifier 194 that rectifies the RF to create a DC power supply which is a voltage across a capacitor 196. Isolation transformer 176 isolates the patient. A power FET 198 modulates current from a primary winding 200 of isolation transformer 176 to a secondary winding 202. A comparator 204 detects when the voltage is at a desired current level and then enables timing circuit 206. Timing 25 circuit 206 generates a repetitive waveform that drives power FET 198.

In Figure 17, coagulation waveform 192 of the isolation transformer output across an output load resistor is shown. In comparison, Figure 18 illustrates the cutting waveform 190.

30 The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be

exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

5

What is claimed is:

CLAIMS

1. An electrode assembly for a resectoscope, comprising:

a cutting electrode with a distal portion;

a coagulation electrode with a distal portion; and

5 a support frame connected to the cutting and coagulation electrodes, the cutting electrode and the coagulation electrode configured to be coupled to a splitter box, wherein the splitter box is configured to receive an input from a single energy source and the cutting and coagulation electrodes simultaneously receive sufficient energy from the single energy source to the cutting electrode to cut tissue and to the coagulation electrode to coagulate tissue.

10 2. The assembly of claim 1, wherein the cutting electrode distal portion has a loop geometry.

15 3. The assembly of claim 1, wherein the coagulation electrode distal portion has a loop geometry.

4. The assembly of claim 1, wherein the cutting electrode distal portion is a roller ball.

20 5. The assembly of claim 1, wherein the coagulation electrode distal portion is a roller ball.

6. The assembly of claim 1, further comprising:
25 a microporous membrane positioned between the cutting electrode distal portion and the coagulation electrode distal portion.

7. The assembly of claim 1, further comprising:
30 an infusion medium source coupled to the microporous membrane.

8. The assembly of claim 1, wherein the infusion medium source is an electrolytic solution.

9. The assembly of claim 1, further comprising:
5 a dispersion ground pad coupled to the cutting electrode; and
a dispersion ground pad coupled to the coagulation electrode.

10. The assembly of claim 1, wherein the splitter box comprises:
a first coil and a second coil, the first coil configured to receive the input from
the single power source and the cutting electrode is coupled in parallel with the first
coil, wherein the second coil is configured to provide current to the coagulation
10 electrode.

11. The assembly of claim 10, wherein the first and second coils are
inductively coupled to each other while minimizing creation of a bipolar current
between the cutting and coagulation electrodes.

12. The assembly of claim 1, wherein the splitter box comprises:
15 a first coil and a second coil with the first and second coils inductively coupled
to each other while minimizing a creation of a bipolar current between the cutting and
coagulation electrodes, the first coil being configured to receive the input signal from
the single power source and the coagulation electrode is coupled in parallel with the
first coil, wherein the second coil is configured to provided current to the cutting
20 electrode.

13. The assembly of claim 1, wherein the splitter box comprises:
a first coil, a second coil and a third coil inductively coupled to each other
while minimizing a creation of a bipolar current between the cutting and coagulation
electrodes, the first coil being configured to receive an input from the single power

source and the second coil is configured to provide current to the cutting electrode, wherein the third coil is configured to provide current to the coagulation electrode.

14. The assembly of claim 1, wherein the cutting electrode distal portion is smaller than the coagulation electrode distal portion.

5 15. The assembly of claim 1, further comprising:

an insulation surrounding at least a portion of the cutting electrode and an insulation surrounding at least a portion of the coagulation electrode.

16. The assembly of claim 1, further comprising:

10 a monitoring circuit coupled to the cutting and coagulation electrodes that monitors voltage delivered to the cutting and coagulation electrodes.

17. The assembly of claim 16, wherein the monitoring circuit is configured to shut off an output of the cutting electrode when the cutting electrode is not in contact with tissue.

18. The assembly of claim 16, wherein the monitoring circuit monitors 15 impedance of the cutting and coagulation electrodes.

19. A resectoscope, comprising:

a sheath including a sheath lumen, a distal portion and a proximal portion; an electrode assembly including,

20 a cutting electrode;

a coagulation electrode; and

a support frame connected to the cutting and coagulation electrodes, the cutting electrode and the coagulation electrode configured to be coupled to a splitter box, wherein the splitter box is configured to receive an input from a single energy source and the cutting and coagulation electrodes simultaneously

receive sufficient energy from the single energy source to the cutting electrode to cut tissue and to the coagulation electrode to coagulate tissue.

5 20. The assembly of claim 19, wherein a cutting electrode distal portion has a loop geometry.

21. The assembly of claim 19, wherein a coagulation electrode distal portion has a loop geometry.

22. The assembly of claim 19, wherein a cutting electrode distal portion is a roller ball.

10 23. The assembly of claim 19, wherein a coagulation electrode distal portion is a roller ball.

24. The assembly of claim 19, further comprising:
a microporous membrane positioned between a cutting electrode distal portion and a coagulation electrode distal portion.

15 25. The assembly of claim 24, further comprising:
an infusion medium source coupled to the microporous membrane.

26. The assembly of claim 25, wherein the infusion medium source is an electrolytic solution.

27. The assembly of claim 19, further comprising:
a dispersion ground pad coupled to the cutting electrode; and
20 a dispersion ground pad coupled to the coagulation electrode.

28. The resectoscope of claim 19, further comprising:

a visualization apparatus housed in a lumen extending from the sheath distal portion to a proximal portion of a working element.

29. The resectoscope of claim 19, wherein the electrode assembly is slidably positioned in the sheath lumen.

5 30. The resectoscope of claim 19, further comprising:

an electrode assembly advancement device coupled with the handle to advance a cutting electrode distal portion and a coagulation electrode distal portion in and out of the distal portion of the sheath lumen.

10 31. The resectoscope of claim 19, wherein the cutting electrode also provides coagulation, and the coagulation electrode also provides cutting.

32. The resectoscope of claim 19, wherein the cutting electrode is a coagulation electrode.

33. The resectoscope of claim 19, wherein the coagulation electrode is a cutting electrode.

15 34. The resectoscope of claim 19, wherein a cutting electrode distal portion is positioned closer to the sheath proximal portion than a coagulation electrode distal portion.

20 35. The resectoscope of claim 19, wherein a cutting electrode distal portion and a coagulation electrode distal portion are separated by a distance of 0.25 mm to 10 mm.

36. The resectoscope of claim 19, wherein a cutting electrode distal portion and a coagulation electrode distal portion are separated by a distance of 0.25 mm to 6 mm.

5 37. The resectoscope of claim 19, wherein a cutting electrode distal portion and a coagulation electrode distal portion are separated by a distance of 0.25 mm to 3 mm.

38. The resectoscope of claim 19, wherein a cutting electrode distal portion and a coagulation electrode distal portion are separated by a distance of 3 mm or less.

10 39. The resectoscope of claim 19, wherein a distance separating a cutting electrode distal portion and a coagulation electrode distal portion is variable.

40. The resectoscope of claim 19, wherein a cutting electrode distal portion and a coagulation electrode distal portion are in a fixed relationship to each other.

41. The resectoscope of claim 28, wherein the visualization apparatus is a telescope assembly of optics.

15 42. The resectoscope of claim 41, wherein the telescope assembly includes a fiber optic.

43. The resectoscope of claim 28, wherein a proximal portion of the visualization apparatus includes a magnification eyepiece.

20 44. The assembly of claim 19, wherein the splitter box comprises: a first coil and a second coil, the first coil configured to receive the input from the single power source and the cutting electrode is coupled in parallel with the first

coil, wherein the second coil is configured to provide current to the coagulation electrode.

45. The assembly of claim 44, wherein the first and second coils are inductively coupled to each other while minimizing creation of a bipolar current between the first and second coils.

5

46. The assembly of claim 19, wherein the splitter box comprises:
a first coil and a second coil with the first and second coils inductively coupled to each other while minimizing a creation of a bipolar current between the cutting and coagulation electrodes, the first coil being configured to receive the input signal from the single power source and the coagulation electrode is coupled in parallel with the first coil, wherein the second coil is configured to provide current to the cutting electrode.

10

47. The assembly of claim 19, wherein the splitter box comprises:
a first coil, a second coil and a third coil inductively coupled to each other while minimizing a creation of a bipolar current between the cutting and coagulation electrodes, the first coil being configured to receive an input from the single power source and the second coil is configured to provide current to the cutting electrode, wherein the third coil is configured to provide current to the coagulation electrode.

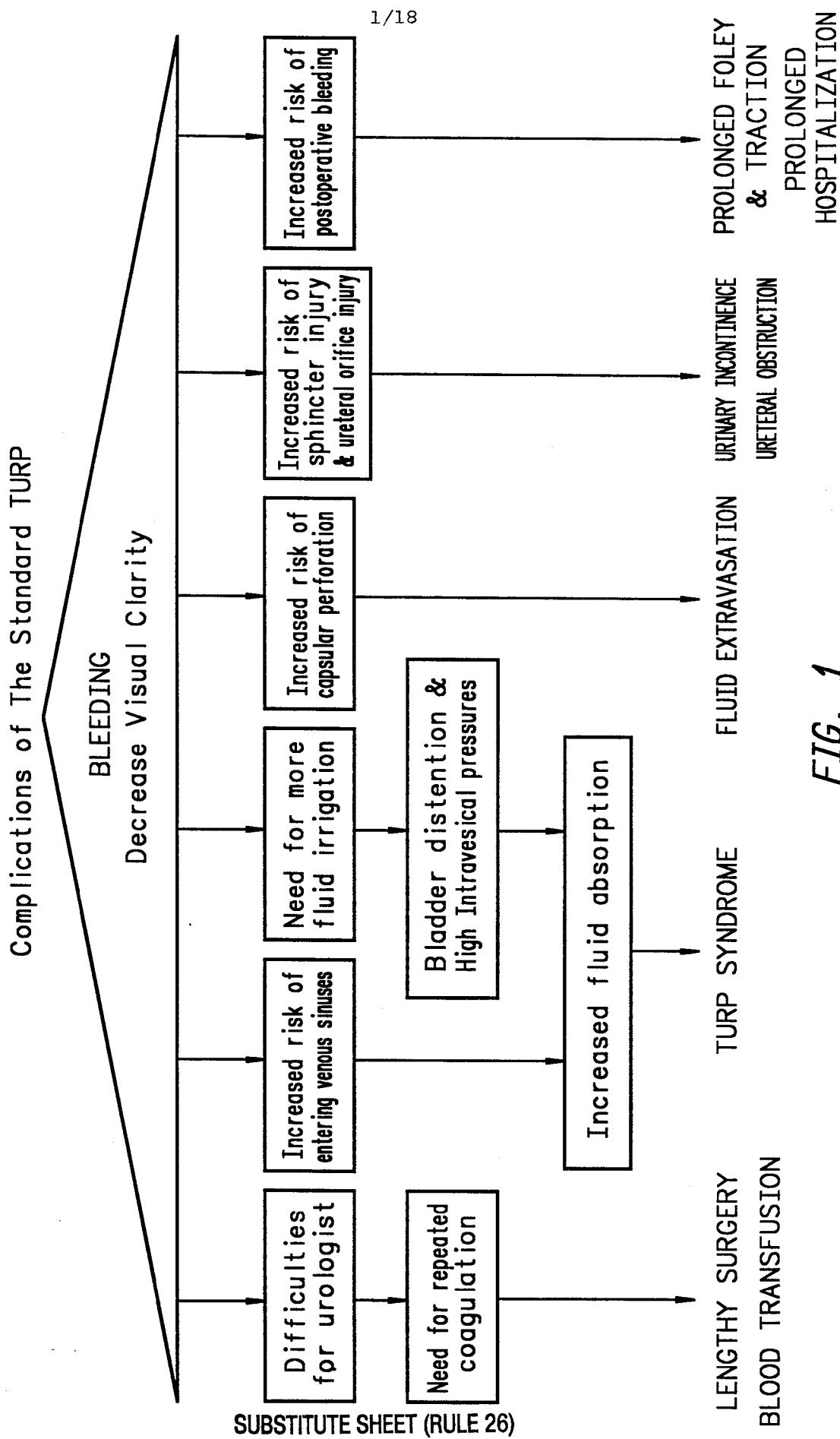
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48. The assembly of claim 19, further comprising:
a monitoring circuit coupled to the cutting and coagulation electrodes that monitors voltage delivered to the cutting and coagulation electrodes.

20

49. The assembly of claim 48, wherein the monitoring circuit is configured to shut off an output of the cutting electrode when the cutting electrode is not in contact with tissue.

50. The assembly of claim 48, wherein the monitoring circuit monitors impedance of the cutting and coagulation electrodes.



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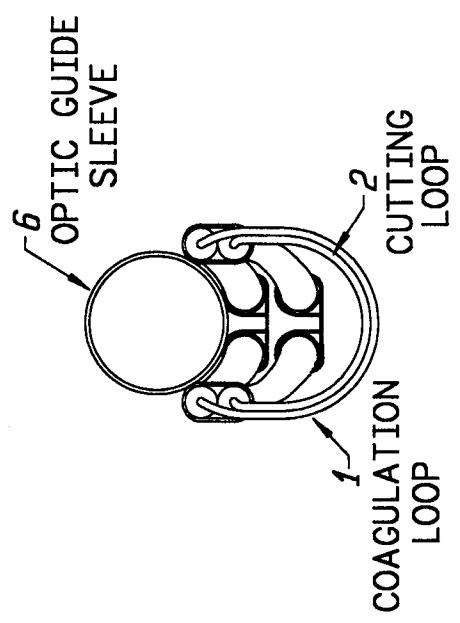
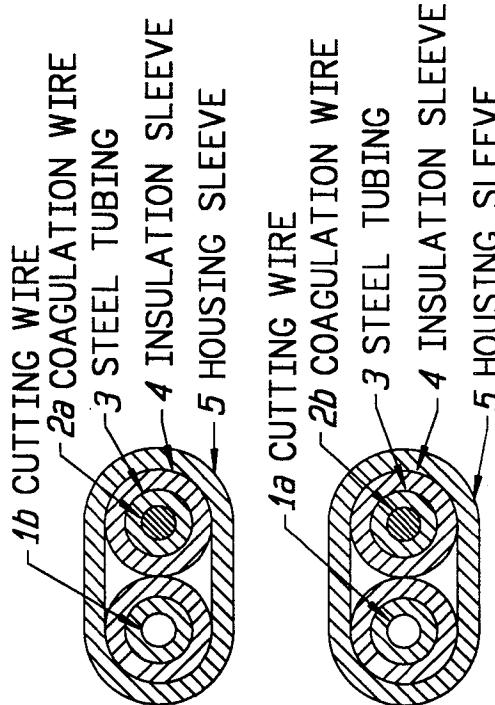
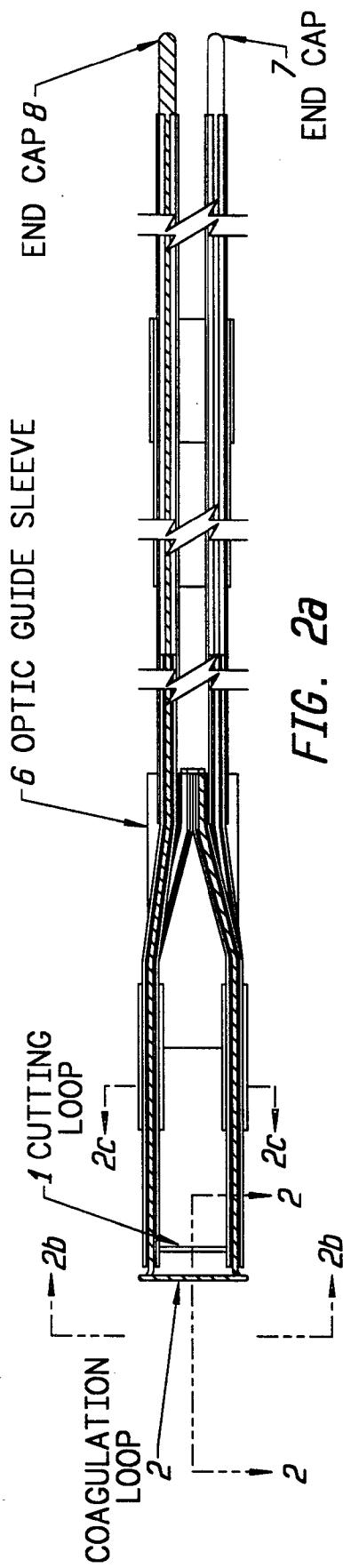


FIG. 2b
FIG. 2c

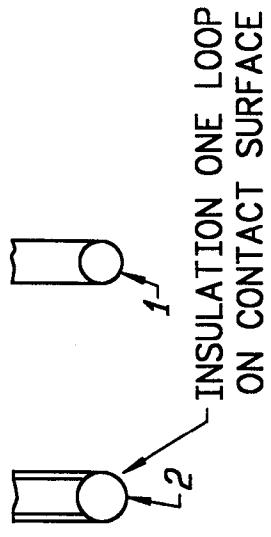


FIG. 2d

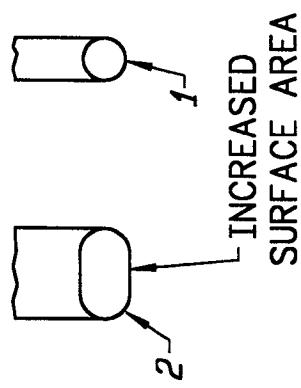


FIG. 2e

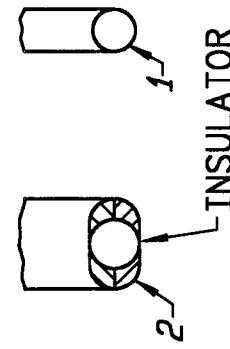


FIG. 2f

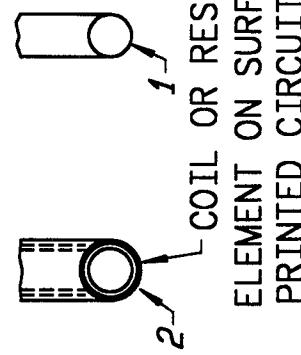


FIG. 2g

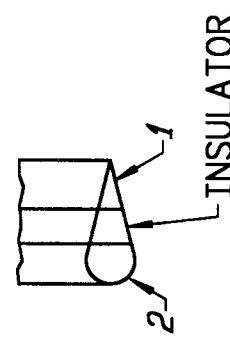


FIG. 2h

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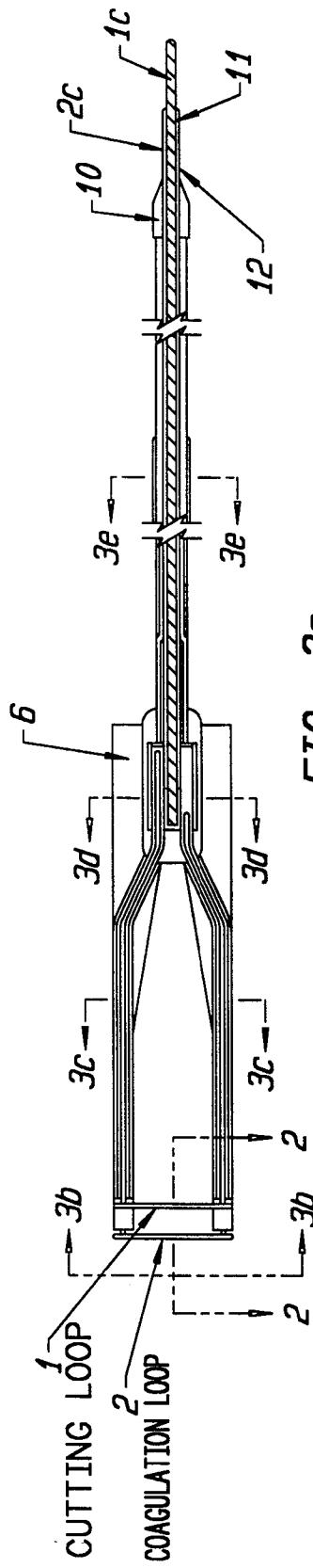


FIG. 3a

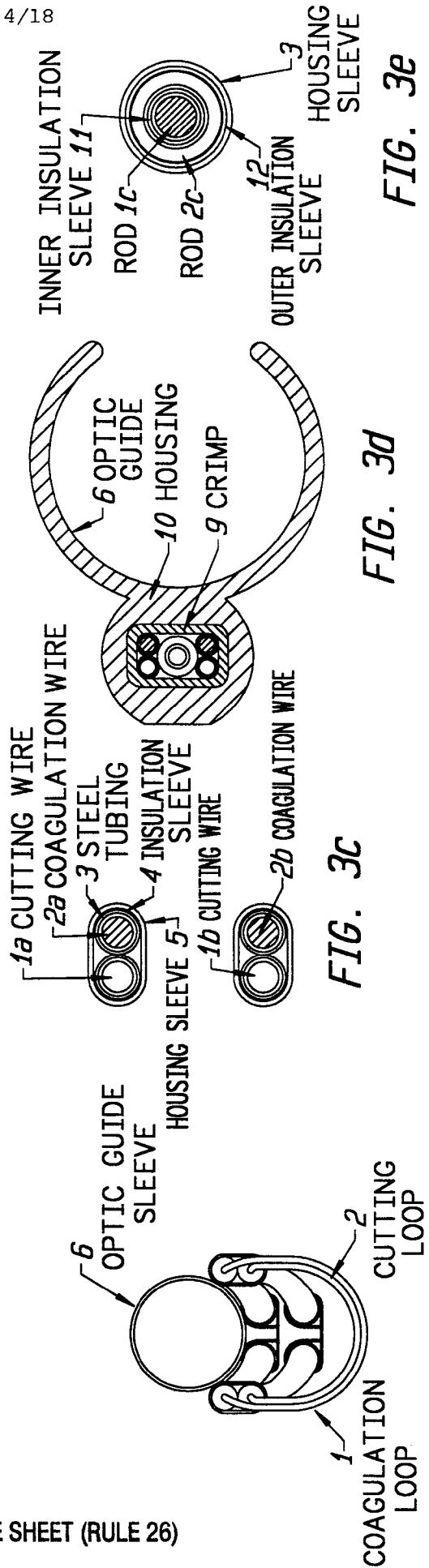


FIG. 3b

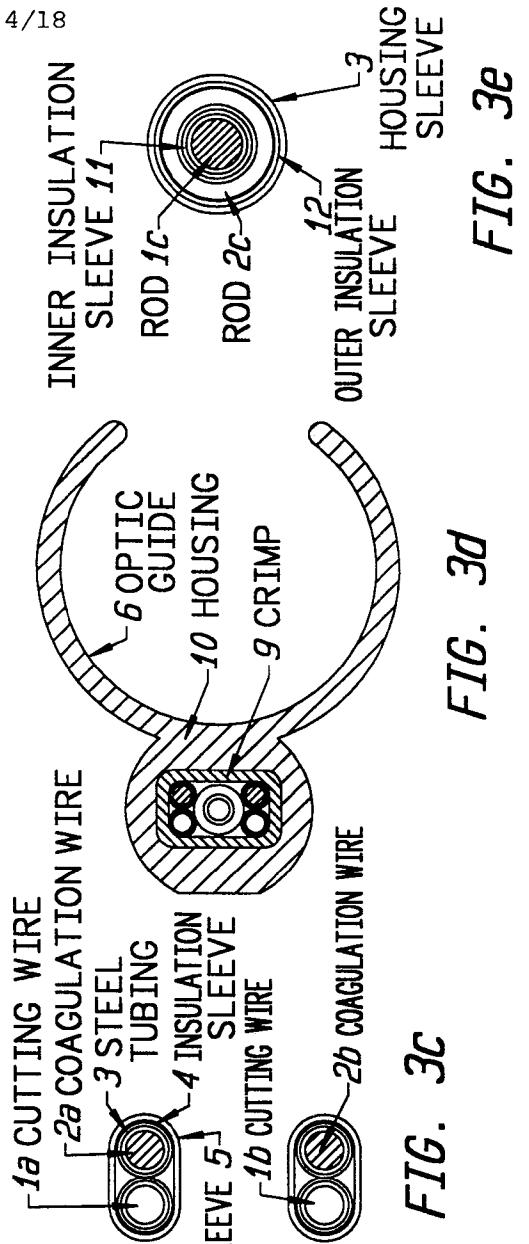


FIG. 3c

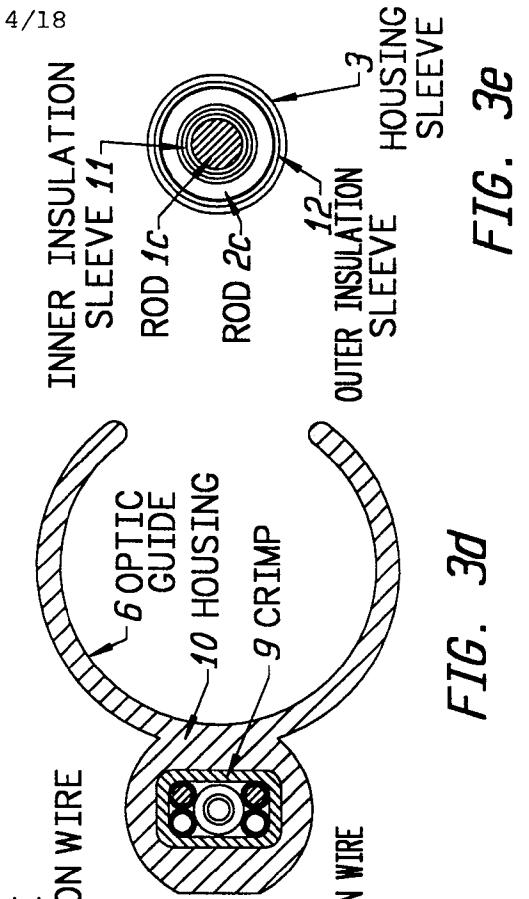


FIG. 3d

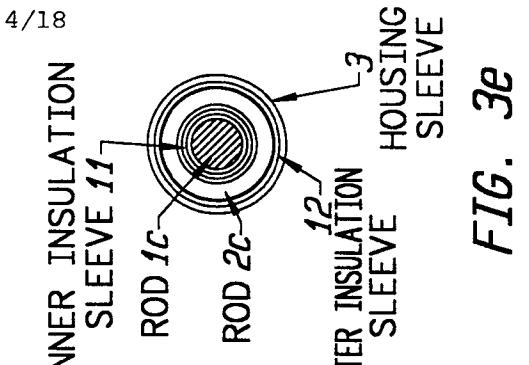


FIG. 3e

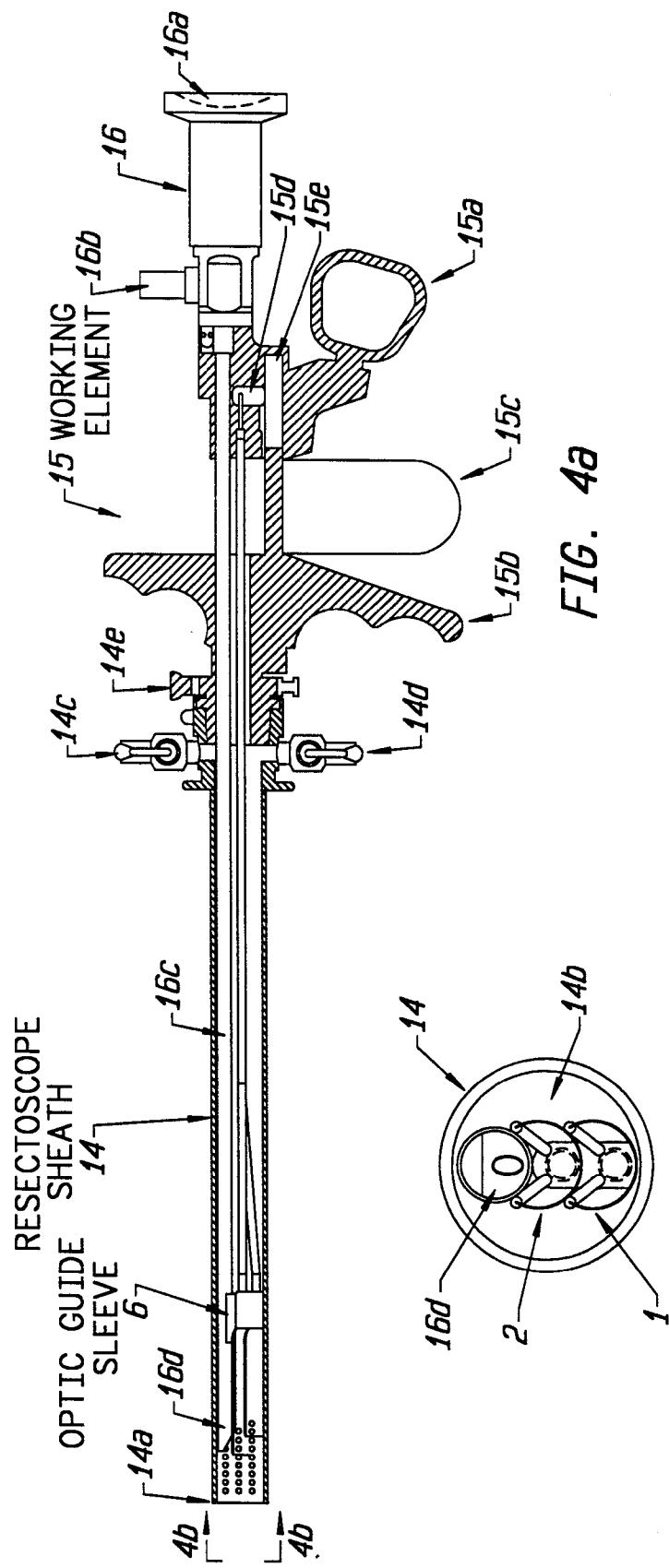
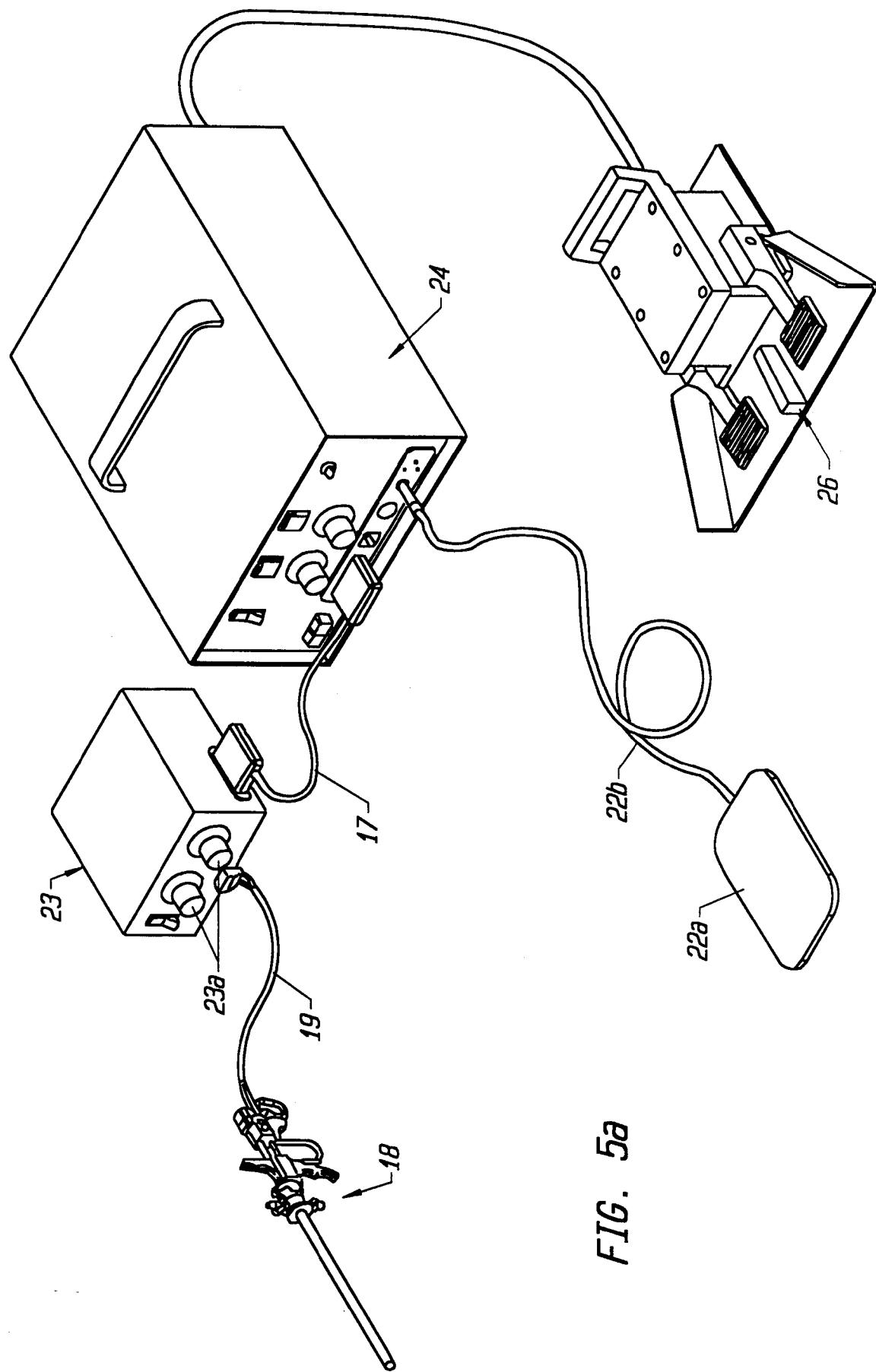


FIG. 4a

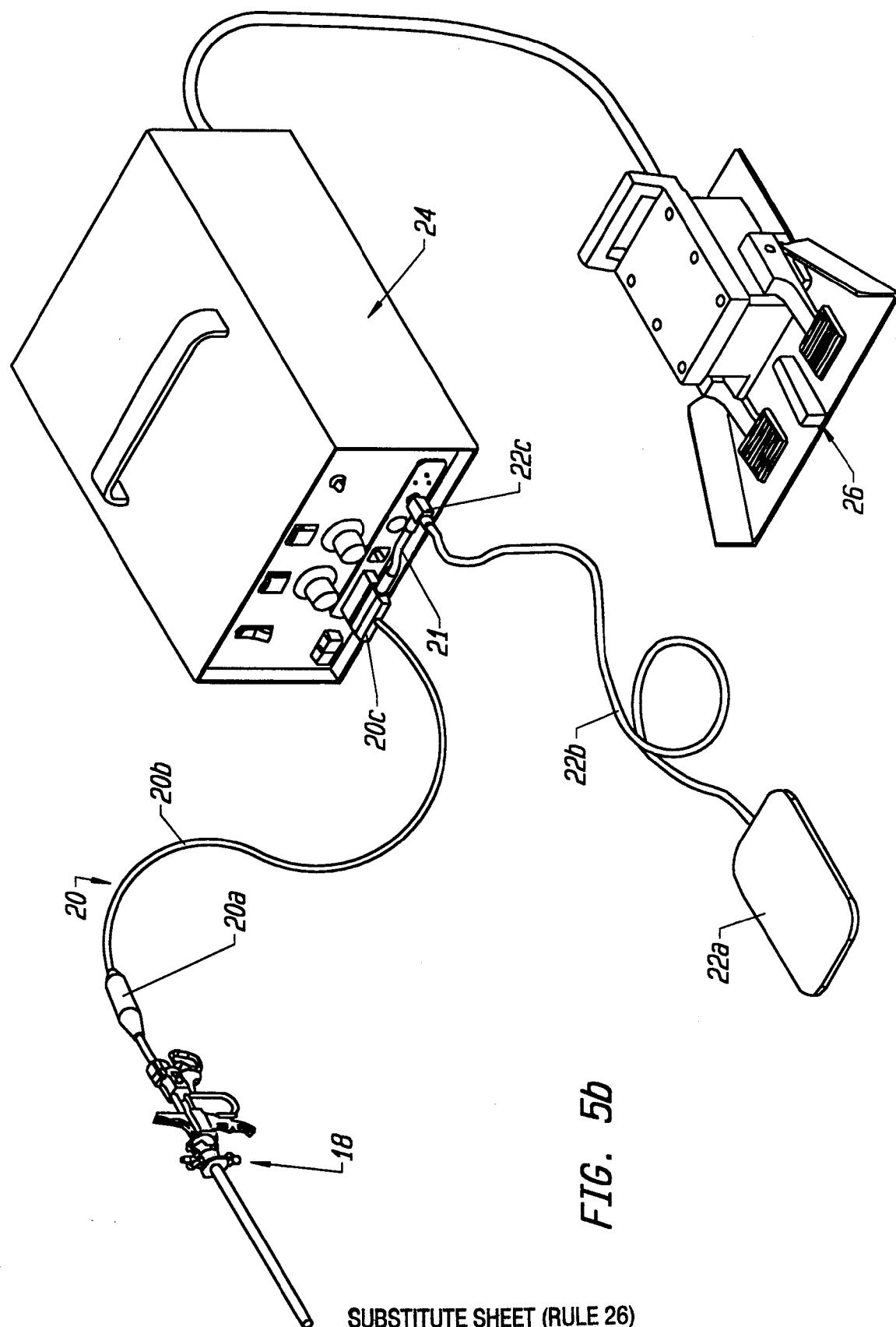
FIG. 4b

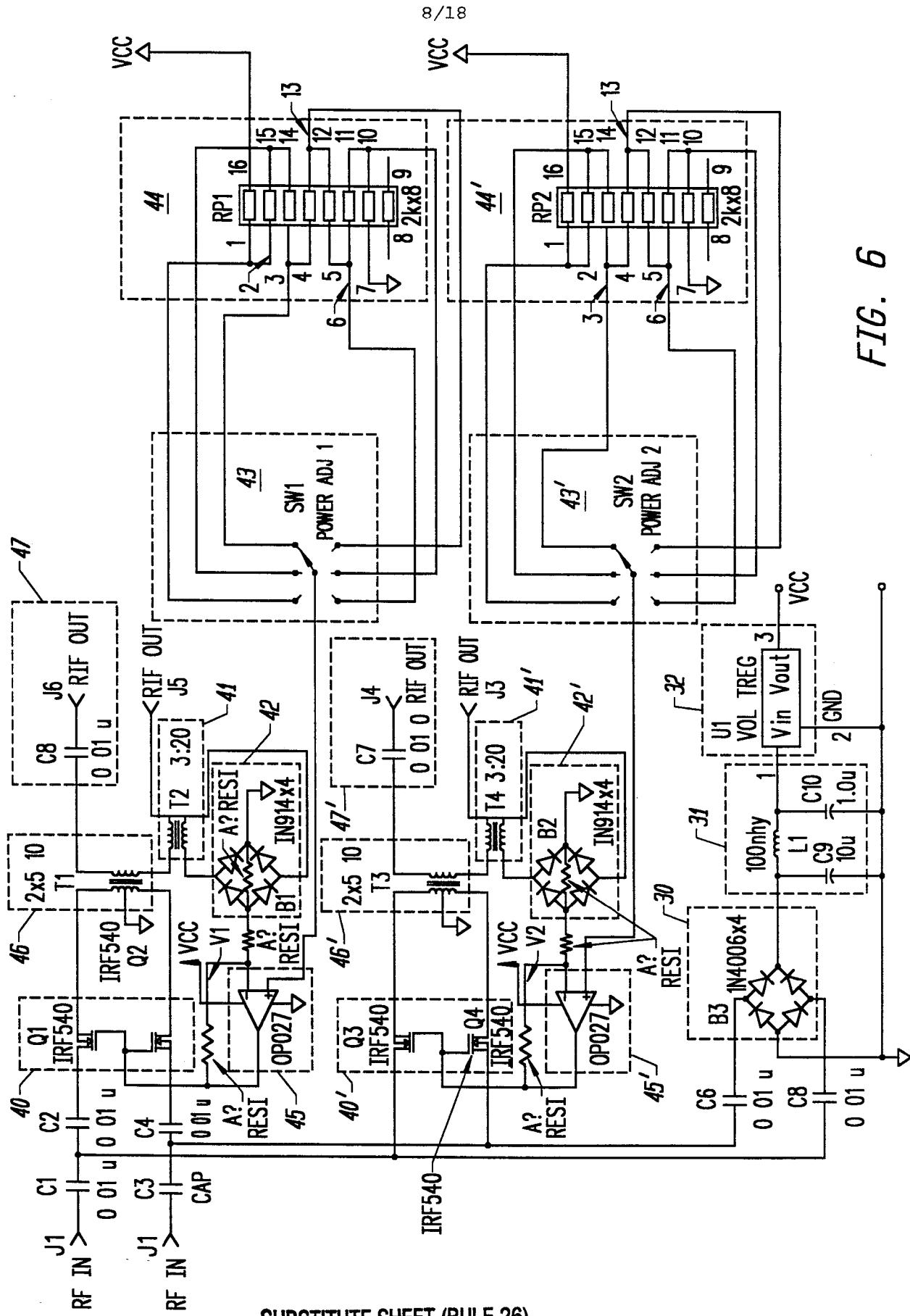
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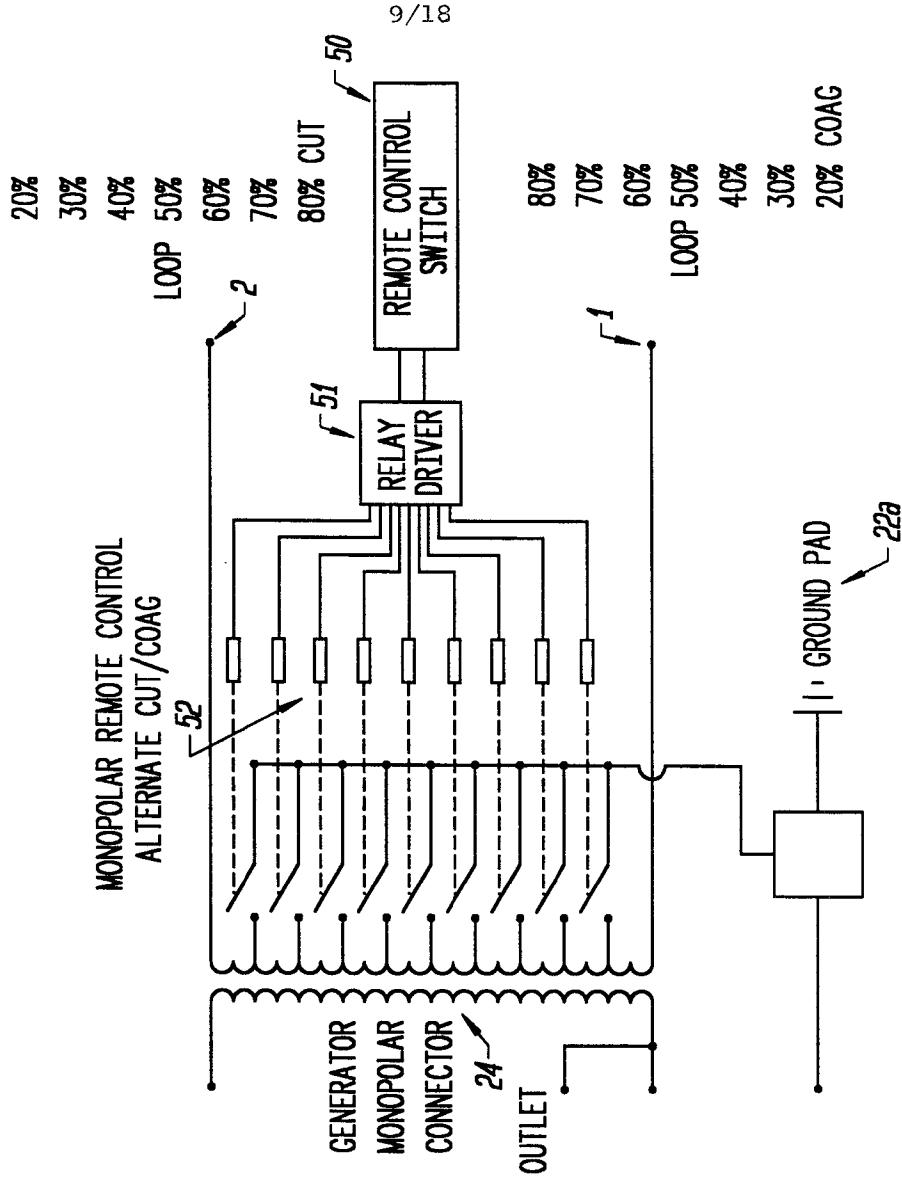


FIG. 8

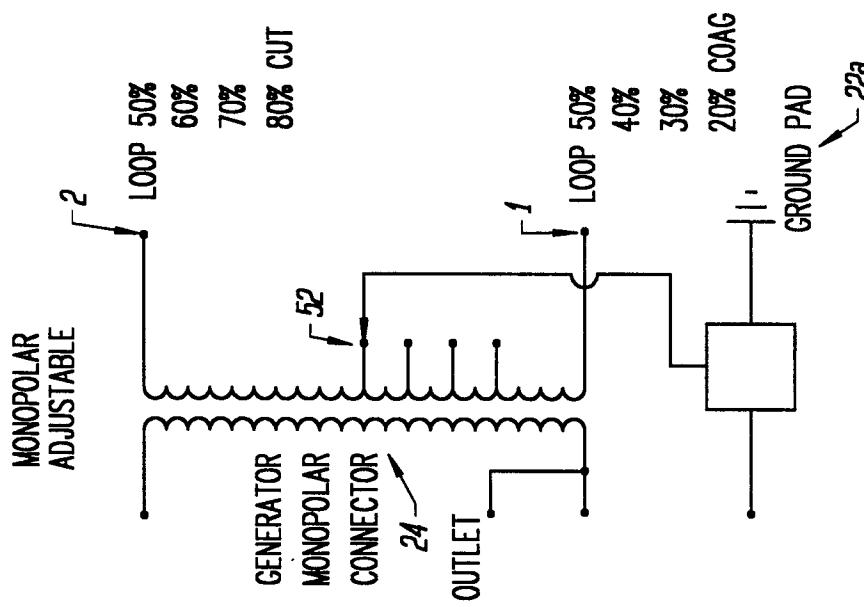


FIG. 7

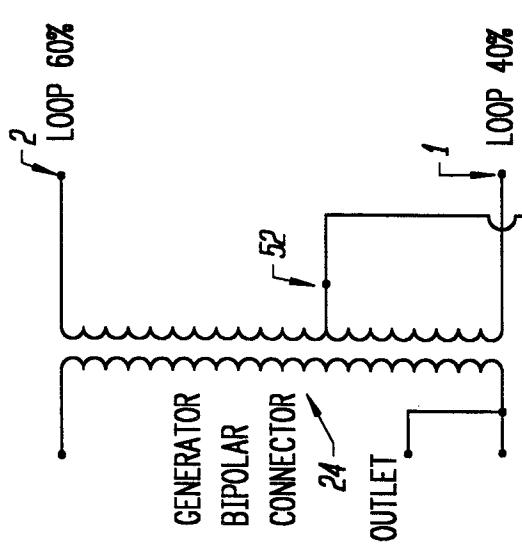


FIG. 9b

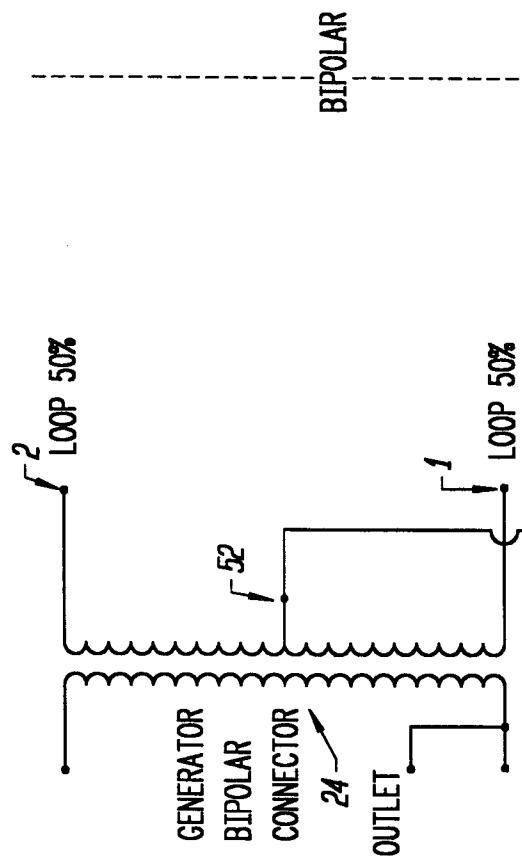


FIG. 9a



FIG. 9d



FIG. 9c

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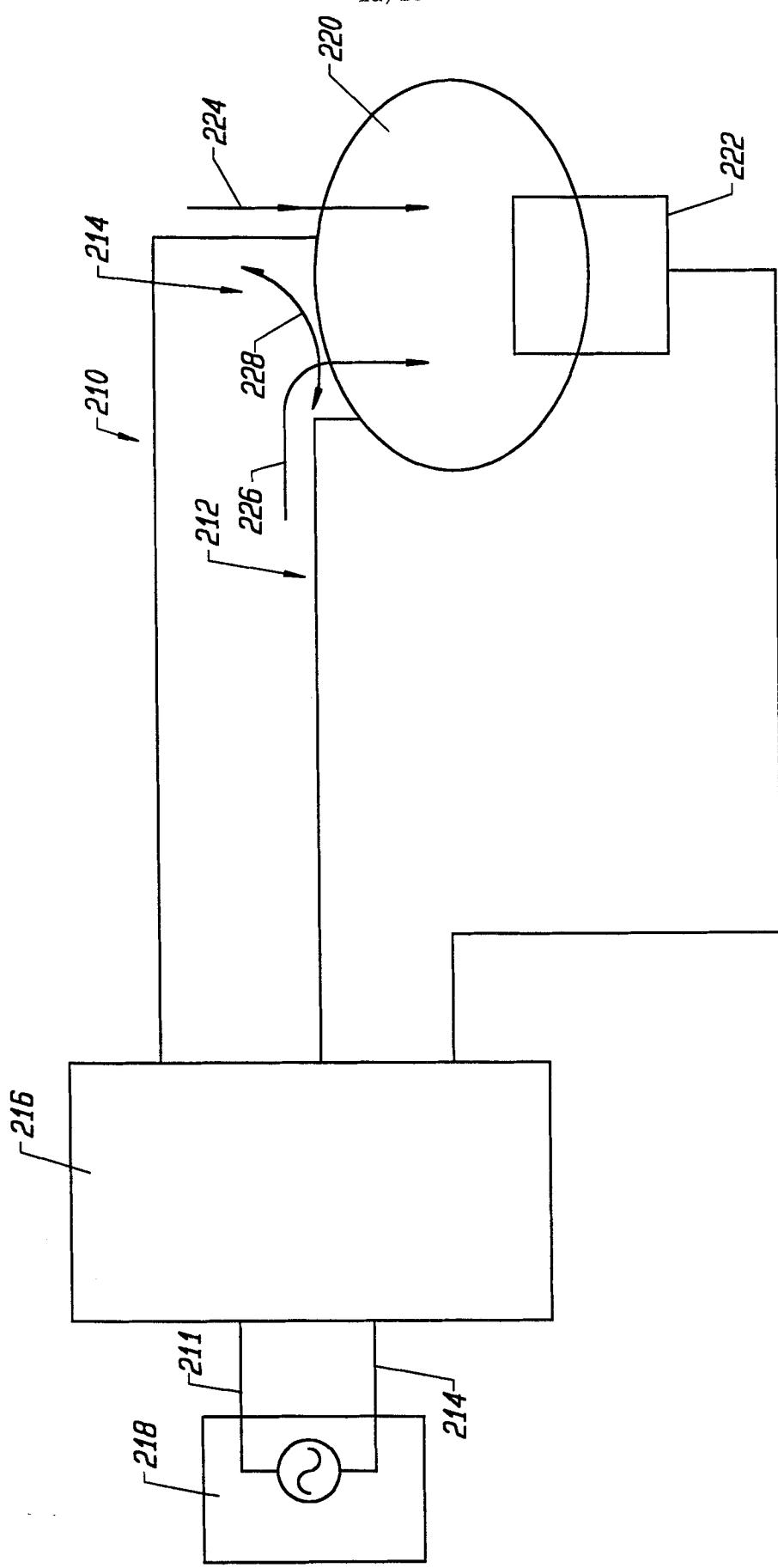
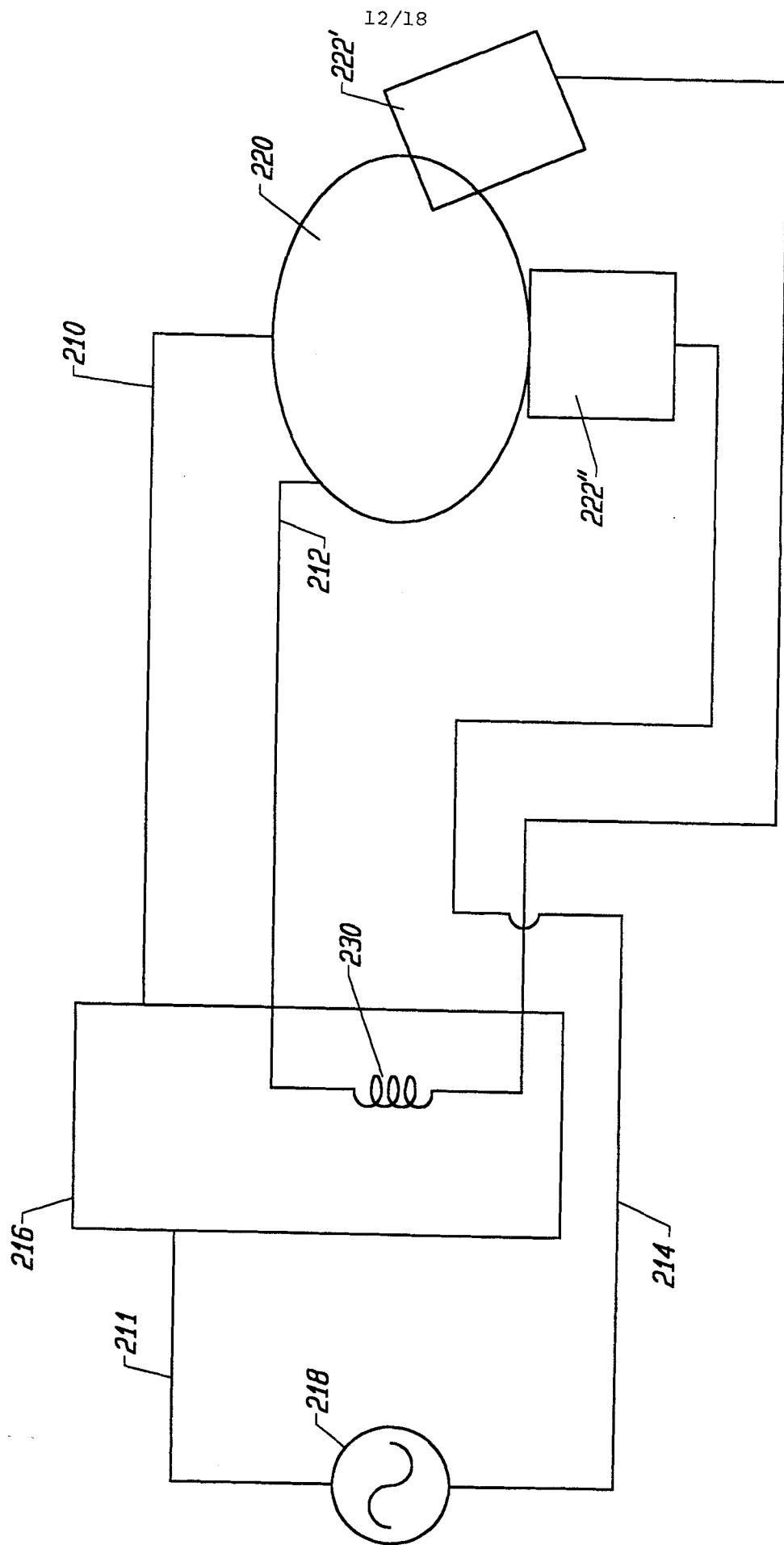


FIG. 10



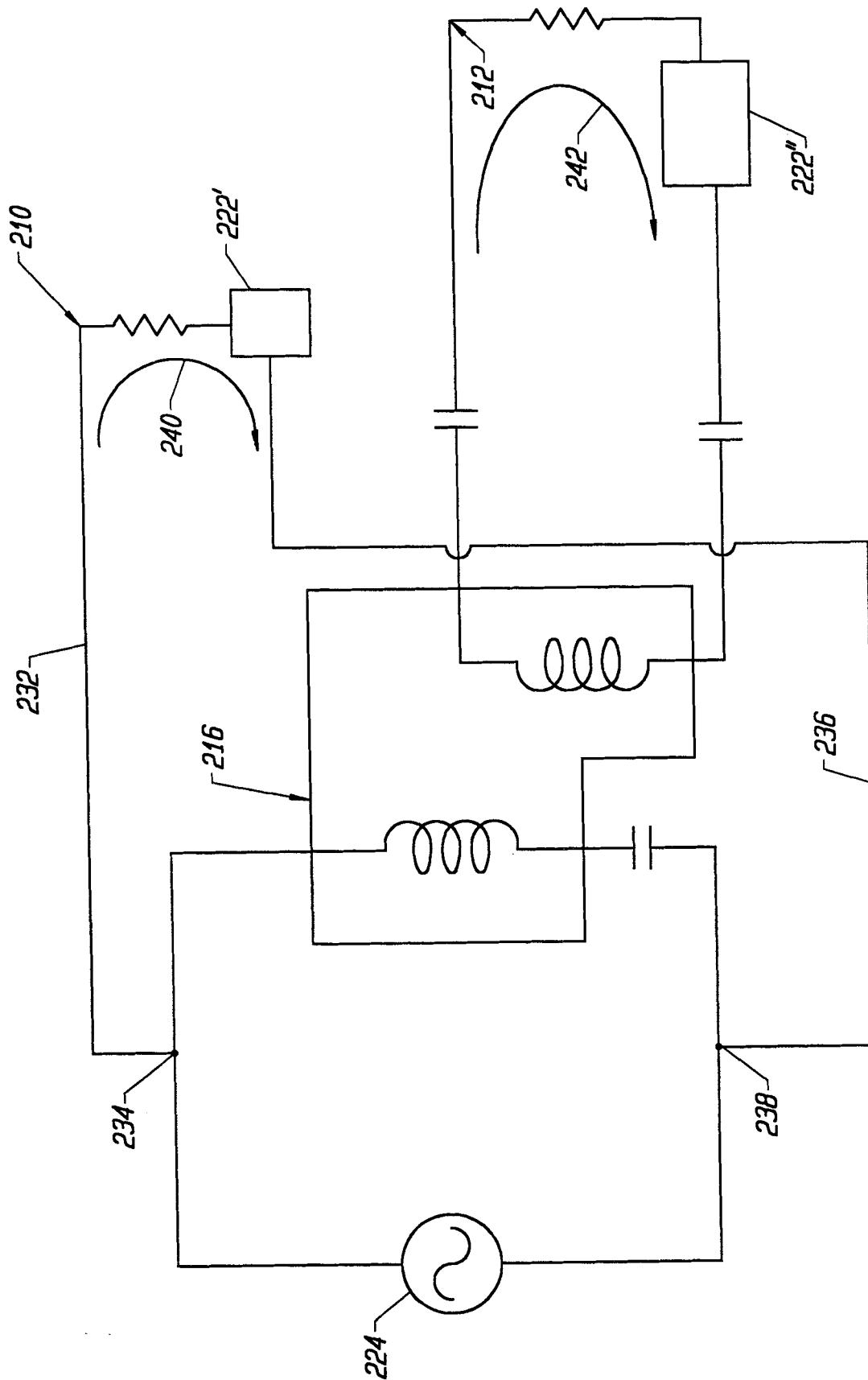
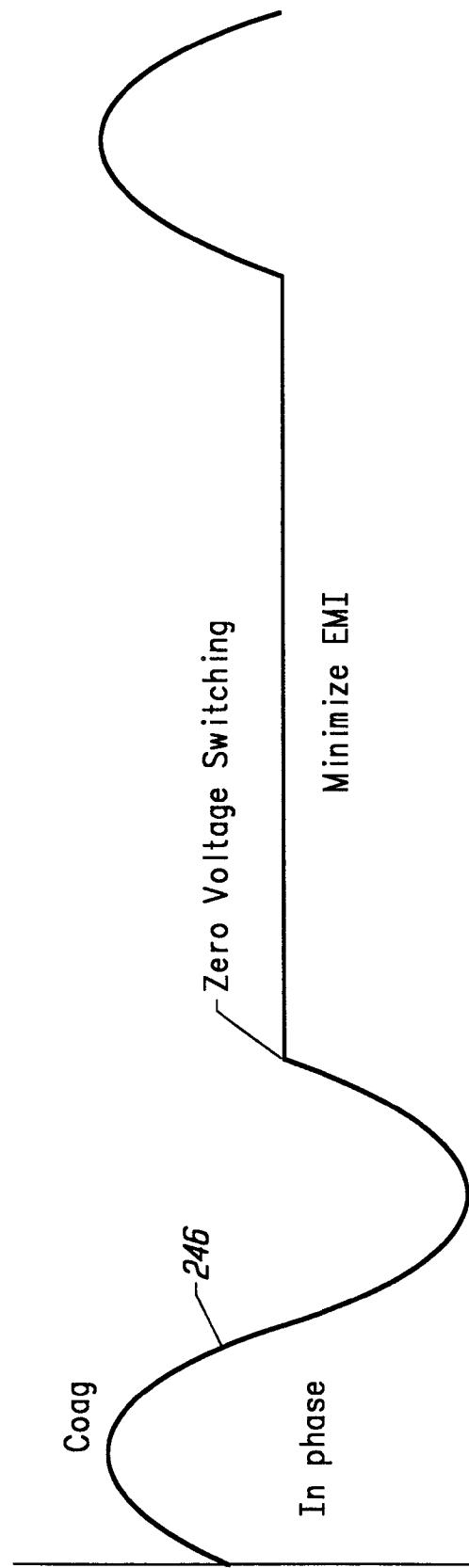
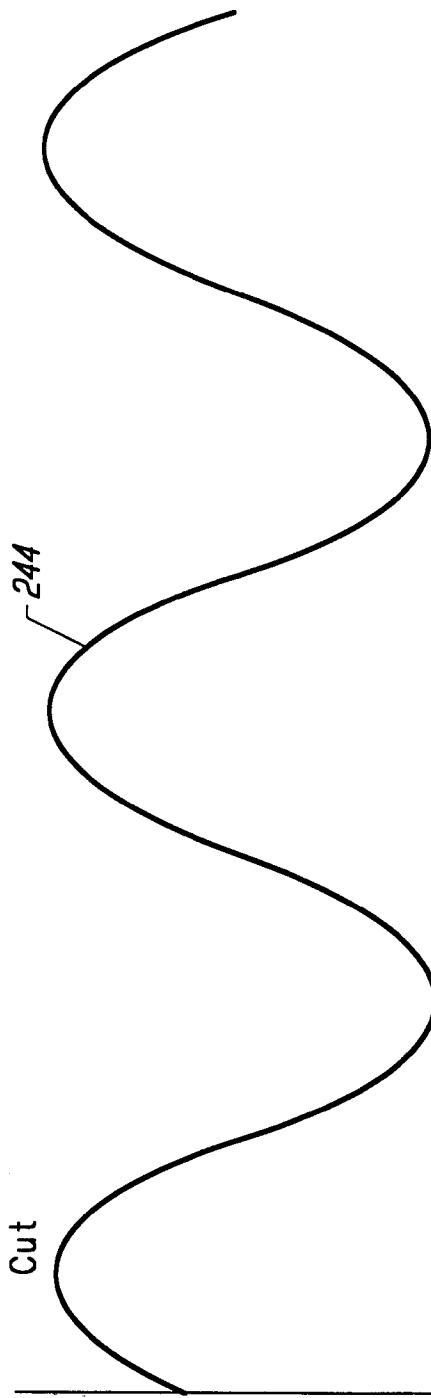


FIG. 12

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FIG. 13a



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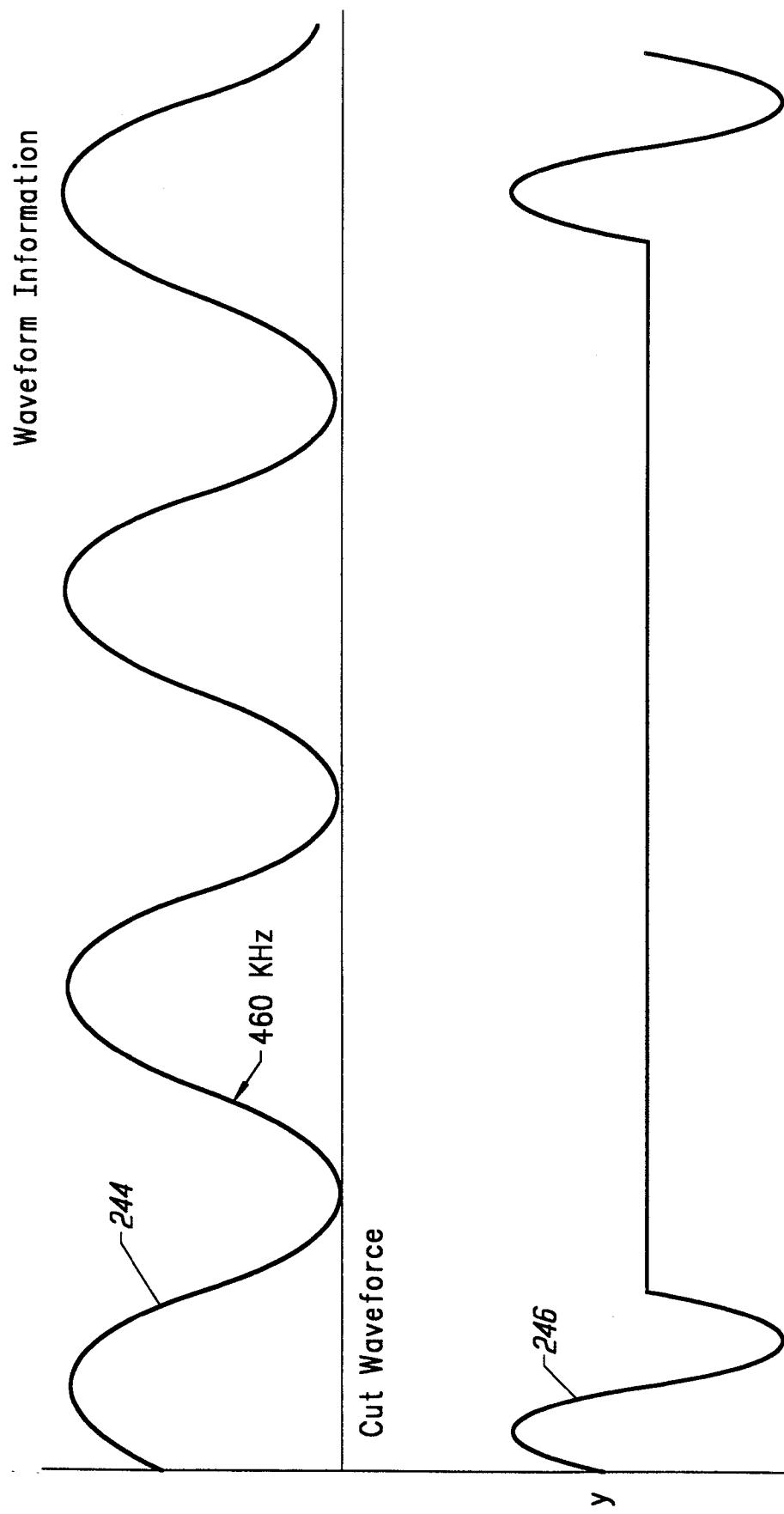


FIG. 14
Prior Art

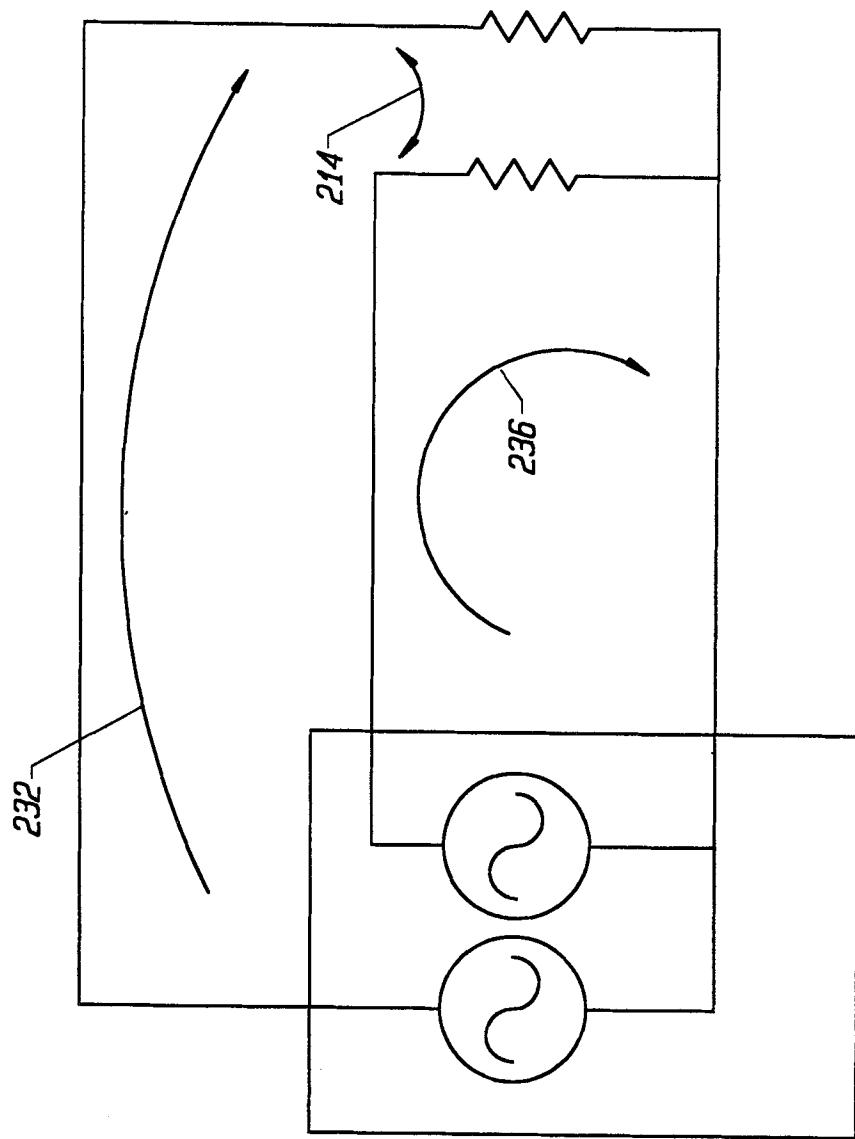


FIG. 15

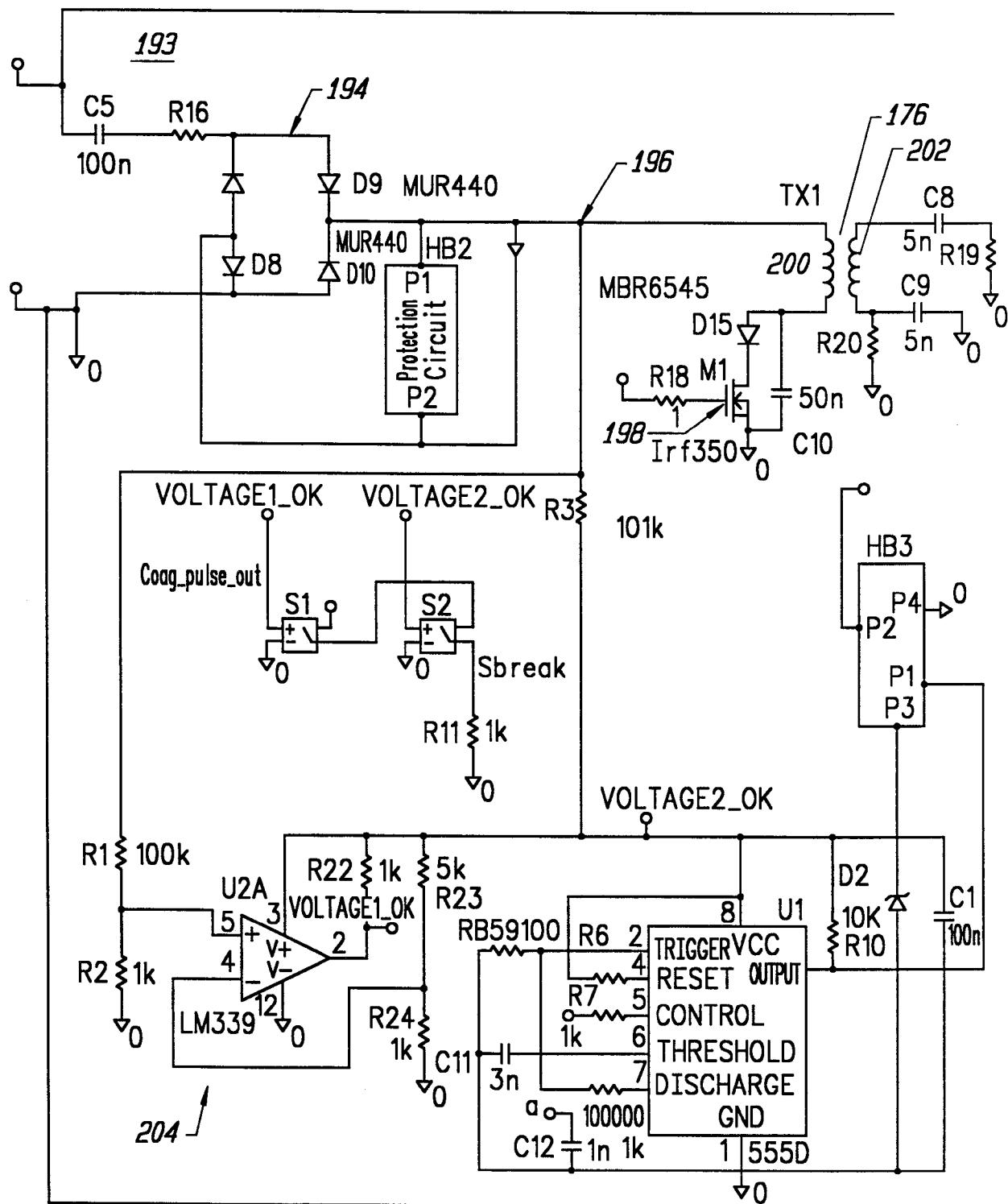
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FIG. 16
SUBSTITUTE SHEET (RULE 26)

FIG. 17a

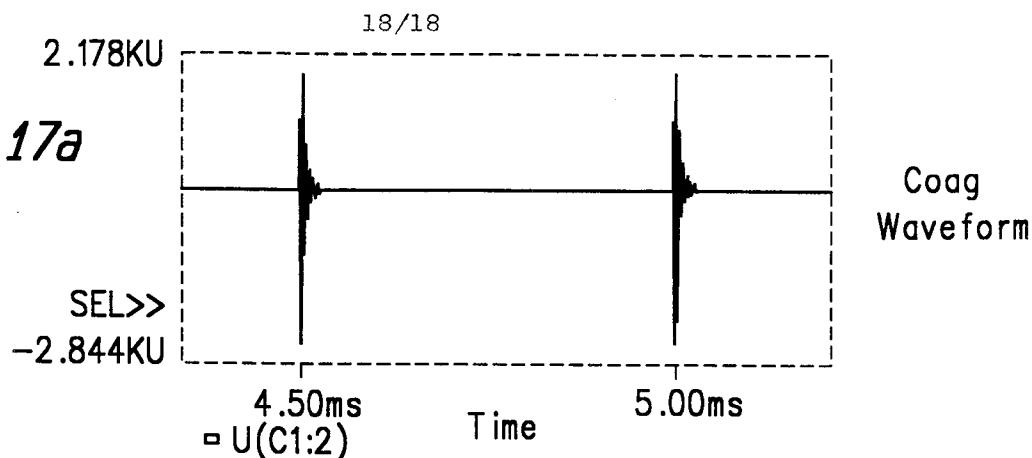


FIG. 18a

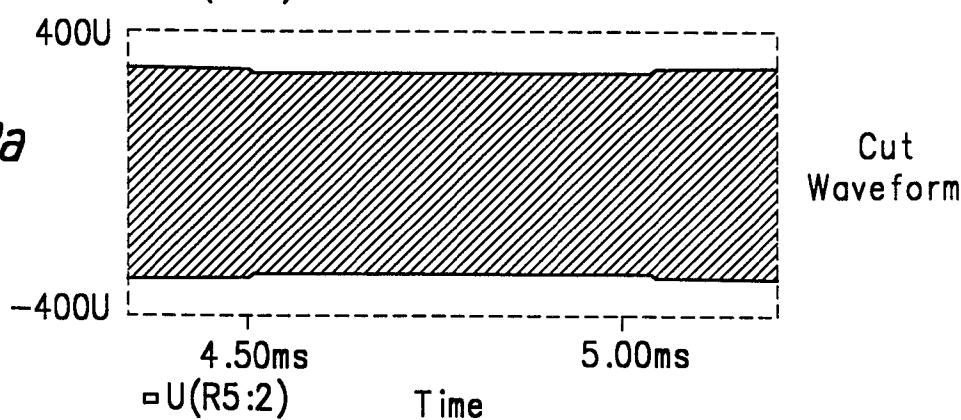


FIG. 17b

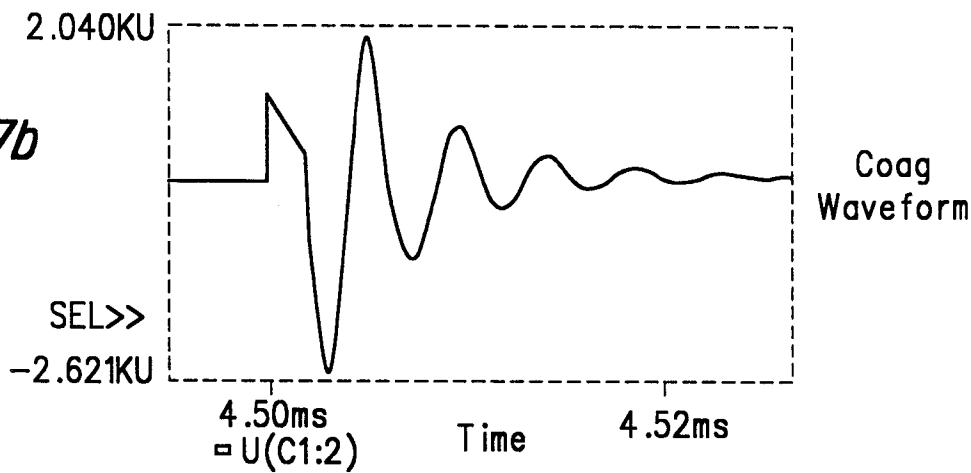
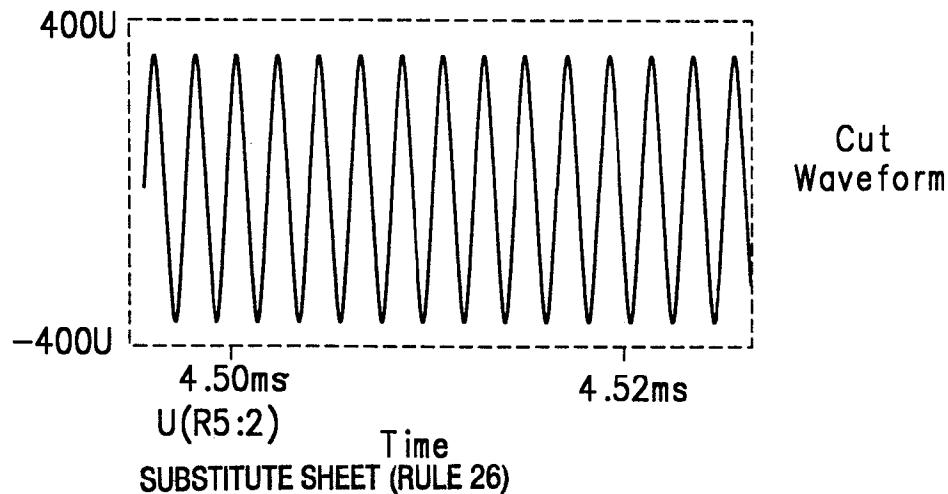


FIG. 18b



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/04495

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/32

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 37156 A (ISSA MUTA M) 28 November 1996 cited in the application	1-5, 9, 14-23, 27-43, 48-50
Y	see page 6, line 33 - page 7, line 6 see page 11, line 32 - page 12, line 19; figures 1-9 ---	6-8, 24-26
Y	US 5 569 241 A (EDWARDS STUART D) 29 October 1996 see abstract ---	6-8, 24-26
X	EP 0 310 431 A (CAVITRON INC) 5 April 1989 see column 5, line 2 - line 38; figure 1 ---	1, 19 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

[°] Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

23 June 1998

03/07/1998

Name and mailing address of the ISA

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Authorized officer

Hansen, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/04495

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 556 397 A (LONG GARY ET AL) 17 September 1996 see abstract; figure 1 ---	1,19
A	EP 0 754 437 A (GYRUS MEDICAL LTD) 22 January 1997 see abstract; figures 1-10 ---	1,16,18, 19,48,50
P,X	WO 97 43967 A (BENDEREV THEODORE V) 27 November 1997 see the whole document ----	1-50
P,X	WO 97 23169 A (VIDACARE INTERNATIONAL INC ;ISSA MUTA M (US)) 3 July 1997 see the whole document ----	1-50

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/04495

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 9637156	A 28-11-1996	US 5658280	A	19-08-1997	
		AU 1335097	A	17-07-1997	
		WO 9723169	A	03-07-1997	
US 5569241	A 29-10-1996	US 5505730	A	09-04-1996	
		AU 2871795	A	19-01-1996	
		AU 2998195	A	19-01-1996	
		CA 2193964	A	04-01-1996	
		EP 0767629	A	16-04-1997	
		NL 1000670	C	22-04-1996	
		NL 1000670	A	27-12-1995	
		WO 9600041	A	04-01-1996	
		WO 9600042	A	04-01-1996	
		US 5558672	A	24-09-1996	
		US 5575788	A	19-11-1996	
		US 5681308	A	28-10-1997	
		US 5746224	A	05-05-1998	
EP 0310431	A 05-04-1989	US 4931047	A	05-06-1990	
		AT 113457	T	15-11-1994	
		AU 616699	B	07-11-1991	
		AU 2538288	A	18-04-1989	
		CA 1323665	A	26-10-1993	
		DE 3852005	D	08-12-1994	
		DE 3852005	T	09-03-1995	
		DK 261589	A	29-05-1989	
		ES 2064360	T	01-02-1995	
		IE 67810	B	01-05-1996	
		JP 6042893	B	08-06-1994	
		JP 2501894	T	28-06-1990	
		NO 300755	B	21-07-1997	
		WO 8902725	A	06-04-1989	
		US 5015227	A	14-05-1991	
US 5556397	A 17-09-1996	NONE			
EP 0754437	A 22-01-1997	AU 5613296	A	09-01-1997	
		AU 6132196	A	22-01-1997	
		CA 2179144	A	24-12-1996	
		EP 0771176	A	07-05-1997	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/04495

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP 0754437 A		WO	9700647 A	09-01-1997
		JP	9010223 A	14-01-1997
		AU	6132096 A	22-01-1997
		EP	0833593 A	08-04-1998
		WO	9700646 A	09-01-1997
		AU	1103797 A	28-07-1997
		WO	9724073 A	10-07-1997
WO 9743967 A	27-11-1997	AU	3008197 A	09-12-1997
WO 9723169 A	03-07-1997	AU	1335097 A	17-07-1997
		WO	9637156 A	28-11-1996